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MARYLAND PHARMACIST

January 1995

Vol. 71, No. 1

Homeopathic
Pharmacist

CE: New
Antivirals and GI
Products

Board Oversight

1995 MPhA
Mid-Year Meeting

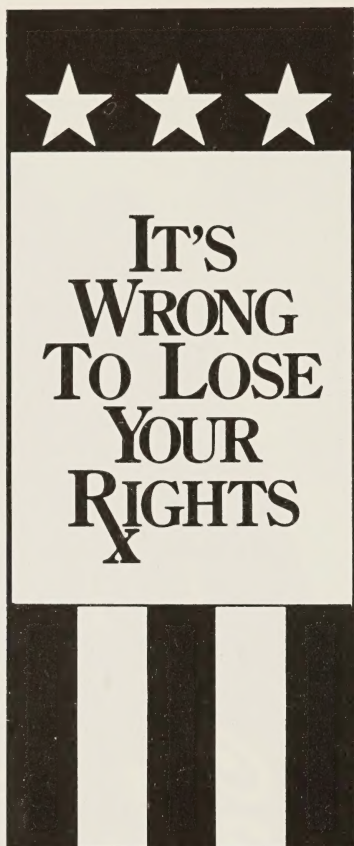
Interactions with
the School

Learning from
Past Mistakes



*Can You
Keep a
Secret?*

MPHA Honor Roll



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MARYLAND PHARMACIST

The Official Publication of The Maryland Pharmacists Association

January 1995

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If you thought that you knew everything about pharmacy, think again. This month's profile looks at Doug Campbell's unique homeopathic pharmacy practice.

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President's Commentary

An Open Letter to Maryland Pharmacists

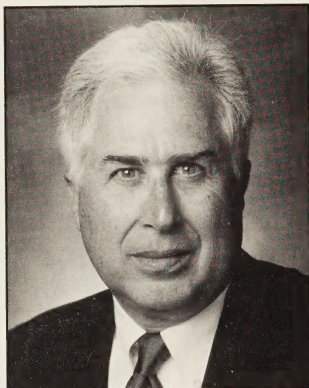
If you're wondering why this month's issue seems different, it's because it is! Because our journal is one of the primary means of communication to MPhA members, the Board of Trustees committed resources to a complete overhaul, redesign, and format change.

But it's not only the look that's changed, it's also the contents. Following the recommendations of a random survey of our members, we recognized that our journal needed to bring you more news and information about what's going on in all facets of Maryland pharmacy. Hospital pharmacists didn't know what issues were important to community pharmacists, and vice-versa. Employee pharmacists wanted more information to help them in daily practice. Everyone wanted to know more about what's going on with the School of Pharmacy and their new programs.

But of all the survey's comments, the one I found most striking was that pharmacists are tired of hearing nothing but bad news about the profession.... what we're not doing, what we are doing that we shouldn't, etc.. It's hard for any of us, regardless of how much money we make or how much we enjoy our profession, to remain positive about the future when so many are telling us that we have no future.

So what's new in *The Maryland Pharmacist*? We have several fresh features -- monthly columns from the Board of Pharmacy and Dean Knapp at the School of Pharmacy. There's a special profile of a Maryland pharmacist that proves pharmacists can still be successful and innovative in their practices. Each month's issue will also have a feature that specifically addresses an important pharmacy practice topic; this month's topic is patient confidentiality, next month's is therapeutic substitution and pharmacist liability.

And although even more changes are in store (local association activity updates, interviews with MPhA officers and trustees, articles from the Maryland Society of Hospital Pharmacists, the American Society of Consultant Pharmacists - Maryland Chapter, our independent buying groups, and the Maryland Association of Chain Drug Stores) we've kept some old favorites. Each issue includes our litigation update from national columnist, pharmacist and attorney David Brushwood.



Arnold Davidov, P.D.
1994-1995 MPhA President

And of course there's at least one credit hour of continuing education every month. I am especially pleased to tell you that CE credits for MPhA members are *FREE*. All you have to do is complete the quiz and return it to the offices each month. It's a simple way to earn 12 credits each year at no charge!

But there's something even more different about *The Maryland Pharmacist*. MPhA's Board of Trustees has committed to sending our magazine to every pharmacist in the state for one year -- regardless of whether they are members or not. The Board recognized that we cannot expect to grow our membership unless we show non-members what the Association does and the value it brings to every pharmacist in the state.

So if you're wondering why you got this magazine when you've never seen it before, it's because the Maryland Pharmacists Association wants you -- the non-member -- to see what we do and why you should belong. I hope that after a few issues, you'll recognize that membership in your state pharmacist association is not only a good idea, it's a great idea!

And if you're not sure if you're a member or not, just look at your address label. If it has a "M" above your name, you're a member. If it has a "NM," you're not. But we hope you will be soon!

MP

Can You Keep A Secret?

Maryland's Patient Confidentiality Requirements

*David G. Miller, P.D., Executive Director
Maryland Pharmacists Association*

In 1992, the Maryland General Assembly enacted one of the most comprehensive medical records confidentiality acts in the country. These statutes were created because the legislature recognized the need to protect an individual's right to privacy in their health care.

Included in the law (Maryland's Health General Article § 4-301-309) were guidelines for disclosure of medical records, to whom and how they may be disclosed, and extensive guidelines for the protection of health information that pertained to mental illness. At the time the law was enacted, it was assumed that prescription orders were considered medical records under the general definition included in the law.

In 1993, the Maryland State Board of Pharmacy, at the request of the Maryland Pharmacists Association, reviewed two issues where the sharing of prescription information might constitute a violation of what we, as professionals, believe to be a right to confidentiality. While the Board's *opinion* was that prescriptions should be held and treated in a confidential manner, they also indicated that the statutory support for that opinion was in question.

Judge John Fader of the Baltimore County Circuit Court researched this issue for the pharmacy community. Judge Fader, a pharmacist as well as an attorney, indicated that indeed it did appear that prescriptions may not be under the jurisdiction of the confidentiality laws. He recommended that the Association seek specific legislation which would ensure patient's rights to privacy and to provide guidance to pharmacists and pharmacies.

Imagine. If a doctor writes a prescription order and makes a notation in his or her patient's chart, that information is considered confidential and subject to the statutory protection. However, somewhere between the patient's departure from the physician's office and their arrival at the pharmacy, the information on that piece of paper ceases to be confidential!

MPhA's Health Care Policy and Legislative Committee looked long and hard at this issue. On the one hand, including prescription records in the Confidentiality Act meant additional responsibilities for pharmacists. On the other hand, as the profession moves towards pharmaceutical care, it was recognized that pharmacists must be perceived and recognized as health care professionals. If our records are not confidential, then the information we keep is essentially no different than that of an electrician, plumber, or salesman of products or services. Clearly, MPhA needed to take the lead on fighting for this issue for the long-term benefit of pharmacists.

During the 1994 legislative session, MPhA worked with Senator Paula Hollinger and Delegate Virginia Thomas to introduce legislation to specify that prescriptions are, indeed, medical records that should be kept confidential. This legislation, which passed unanimously, caused many Maryland legislators to remark that they thought prescriptions were already covered!

What the Law Says

House Bill 346 and Senate Bill 32, the legislature assigned numbers to the "Prescription Confidentiality Act", amended the Maryland Pharmacy Act. The new language is straightforward:

§ 12-505

(1) In each pharmacy, a record of each prescription prepared or dispensed in the pharmacy shall be made and kept on file for at least 5 years.

(2) The records and files maintained by a pharmacy of prescription orders for drugs, medicines and devices that identify or may be readily associated with the identity of a patient: (i) are medical records; and (ii) may only be disclosed in accordance with the provisions of Title 4, subtitle 3, of the Health-General Article.

Disclosure

Section 4-304 of the Confidentiality Act provides substantial, detailed guidelines for disclosure of medical records. For example, authorization from the patient is required. That authorization must be in writing, dated, and signed by the patient; it also must include the name of the health care provider (pharmacist or pharmacy in our case) and the type of information requested by the patient. The Act permits a reasonable copying charge to be levied by the provider for the provision of the information.



Signing the Patient Confidentiality Act

Seated, left to right: Senate President Mike Miller, Governor Schaefer, House Speaker Casper Taylor. Standing, left to right: Delegate Virginia Thomas, MPhA Lobbyist Robin Sbaivitz, Board of Pharmacy Executive Director Roslyn Scheer and Commissioner Dorothy Levi.

Except in certain unusual circumstances, those generally surrounding mental health treatment and therapies, it is illegal for a health care provider to refuse to disclose or provide a copy of the medical record once authorization has been received. Refusal to disclose is a misdemeanor and can result in a fine of \$1,000.

Issues of Confidentiality

How does this legislative change affect pharmacists? There are three major areas where a pharmacist might receive a request to disclose prescription records that would give rise to concerns about patient confidentiality.

1

Inspections and Audits

Aside from patient's asking for prescription profiles, the most common request for access to pharmacy records comes from two sources: Board of Pharmacy and Division of Drug Control inspectors and third-party program auditors.

Both the Medical Records and the Prescription Confidentiality Act specifically permit access to prescription records by the Department of Health and Mental Hygiene's inspectors for the purposes of insuring that health care providers are complying with laws embodied elsewhere in Maryland statute. Therefore, because the Maryland Pharmacy Act specifically

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mandates that the Board of Pharmacy and the Division of Drug Control regularly inspect pharmacies and pharmacists, their inspectors may review any and all prescription records *without* advance authorization from patients.

Prudent pharmacists should, however, always keep copies and note to whom those copies were given for any prescriptions removed from the pharmacy by inspectors. Then, in the extremely rare event that a question should arise about disclosure, documentation will exist to give protection to the pharmacist and practice.

Third-party audits, however, are a completely different matter. When a patient uses a prescription benefit to pay for

their pharmacy services, they authorize disclosure of complete information about that particular prescription to the benefit company's auditors. The written authorization generally occurs twice: once when the patient enrolls in the program and then again when the patient or their agent picks the prescription up and signs the third-party claim log.

While auditors do have a right to review prescriptions for claims you have submitted on behalf of your patients, they *do not* have authorization to review prescriptions for other patients. In other words, while a PCS auditor may review a state employee's prescriptions, they may not look at your prescription records for cash customers, Blue Cross subscribers, etc..

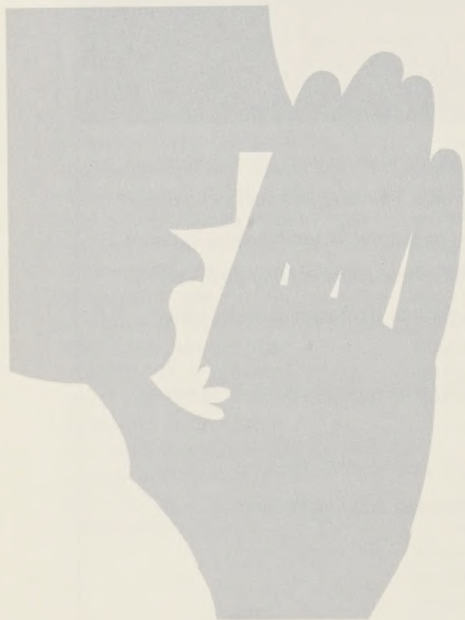
It is your responsibility as the pharmacist to ensure that auditors never "let their fingers do the walking" through your prescription files. (For additional details about third-party audits, see "Surviving a Third-Party Audit" in the November 1994 issue of *The Maryland Pharmacist*.)

2 *Requests from Law Enforcement*

As stated earlier, MPhA first became aware of the deficiencies in the original Medical Records Confidentiality Act after seeking answers from the Board of Pharmacy. One of the questions we had asked pertained to letters sent by a county police unit to pharmacies informing them that they would "periodically conduct an investigative audit of [their] prescription files." The unit's intent was to try and identify prescribers and patients who might be abusing or misusing controlled substances.

The Board of Pharmacy's response was unequivocal. "The Board of Pharmacy advises that [the police unit] has no authority to require a pharmacy to produce records in the absence of a subpoena or search warrant. Although the Board and the Division of Drug Control have the authority to inspect pharmacy records under the Pharmacy Practice Act, there is no parallel authority granted to the police."

Any pharmacist would feel uncomfortable refusing a direct request for prescription information from the police. However, the right of the patient to privacy must be paramount. There are sufficient means for police agencies and law enforcement to obtain prescription records through court warrants or subpoenas.



To give additional emphasis to this area, consider the following. A pharmacist practicing in a local chain had a local police officer approach the counter, present his badge and identification and ask for a print-out on all the prescriptions that had been dispensed for a particular patient. The officer claimed that he was conducting an probe into a series of possible forgeries. After checking with the home office, the pharmacist asked that the officer submit a written request for the information. Needless to say, the officer was furious and harassed the pharmacist for failing to cooperate with his investigation. After a few phone calls between the home office and the officer's superiors, it turned out that there was no probe, no forgeries, no searches. Instead, the officer was trying to obtain information on his former spouse to use in a custody battle.

3

Profiles for Patients

In reality, the average pharmacist's only regular involvement with the Prescription Confidentiality Act is when patients request prescription profiles for tax or insurance purposes. While most of us have treated these requests without much thought in the past, the new protections afforded by legislative changes necessitate a more responsible and accountable attitude.

Obtaining a written request for prescription profiles is one major way to protect yourself and your practice. To make it easy for you, MPhA has developed a special "Prescription Profile Request Form" for you to customize for your pharmacy, duplicate as needed, and provide to your patients.

To minimize disruption, if you have traditionally taken telephone requests for prescription histories, you can still generate the profile and have it available for the patient to pick up. Simply attach a copy of the "Prescription Profile Request Form" to the envelope and have the patient sign the form when they come in. If you provide delivery services and send your profiles out in that manner, you can have your delivery person obtain the signature of the patient at the time of delivery.

The "Prescription Profile Request Form" on page 10 and copies of the Maryland law are "must haves" for every pharmacy practice. Keep them available and use them!

Signed prescription history requests should be maintained on file in the pharmacy. While a separate file is ideal, you may choose to keep these forms with your third-party signature logs.

Final Comments

Maintaining patient confidentiality requires the support of the pharmacy personnel. All technicians, cashiers, bookkeepers, billing agents, and others who have access to patient information should be instructed and educated about the need to preserving confidentiality. Our patients expect that respect from us as health care providers. Maryland law demands it.

MP

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Prescription Profile Request Form

Person Requesting Profile(s) _____

Street Address _____

City/State/ZIPcode _____

Daytime Phone Number _____

Time Period ☐ Year _____ ☐ Month _____

☐ Date Range _____

☐ I will pick the profile(s) up.

☐ Please mail or deliver the profile(s).

Please write the name of the patient for whom you wish to obtain a prescription profile and their relationship to you.

| Patient Name | Relationship |
|--------------|--|
| | <input type="checkbox"/> Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other Dependent |
| | <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other Dependent |
| | <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other Dependent |
| | <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other Dependent |
| | <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other Dependent |

I hereby request and authorize the generation of a confidential prescription profile history for the above specified individual(s). I am authorized by these individuals to obtain this profile for them.

Patient Signature _____

Date of Request _____

Interactions...

A New Monthly Column from the School of Pharmacy

Every pharmacist in Maryland is in the midst of dramatic changes in the world that are affecting everything we do and everything that we value. Whether it is health care, the pharmaceutical industry, drug distribution, or pharmaceutical care, change is everywhere. When people have to change, they often get nervous, fearful and even angry.

At times like this, it is essential to have friends, and pharmacists in Maryland need to talk to each other regularly and often to keep friendships solid. The move by MPhA to provide *The Maryland Pharmacist* to every pharmacist in the state is thus a timely and crucial effort to open lines of communication. Similarly, this new column will link the University of Maryland School of Pharmacy even closer to the profession.

The School's major educational task is to prepare future generations of pharmacists to contribute to the health and well being of society. It is also concerned with providing opportunities for current pharmacists to maintain and enhance their education. Our faculty does this by participating frequently in continuing education programs sponsored by state and local associations. For practitioners who desire a more formal program, over 160 are now enrolled in our nontraditional PharmD pathway, which has rapidly become a national model.

The growth of managed care continues unabated. Maryland now stands third among the states in penetration of managed care. Consolidation within the pharmaceutical industry and new and strange alliances among all sorts of bedfellows are changing the face of drug distribution. Information technology ties the pharmacist to a widening web of data about patients, programs and prescribers.

Every last dollar is being wrung out of drug distribution. Powerful automated warehouses at mail order distribution centers and the increased

liberalization with which legislatures view the use of technicians are decreasing the demand for pharmacists in distribution. Centralized programs to drive prescriptions to generics or to the cheapest therapeutic alternative are adding to pressures in which the only profits from drug distribution will be those associated with distributing products as commodities.



David A. Knapp, Dean
UMAB School of Pharmacy

Pharmacy as a profession cannot survive if its income is dependent solely upon profits from selling medicine. The only way to survive as professionals is to position ourselves where we have belonged all along: in the midst of patient care. Needless to say, it will not be easy to do this, given recent changes. But the move to capitation as the method of choice for financing health care aligns financial incentives with the goals of pharmaceutical care. There will be opportunities for pharmacists to be paid for their brain power!

The possibilities are enormous but as yet unexploited. Drugs remain the number-one intervention of physicians; however, without the value that pharmaceutical care can add, they are but commodities.

A close examination shows that patients --- over half! --- simply don't use a large amount of what is ordered. Some of this is due to noncompliance. Other waste occurs because the drugs prescribed aren't right for the job or cause side effects that could have been anticipated and prevented. Pharmacy associations such as the Maryland Pharmacists Association, in partnership with the School of Pharmacy, can take the lead with ways in which pharmacy can help health care reformers design a system to improve the use of drugs in patients, meet the goals of cost management and provide pharmacists a share of the savings generated.

MP

Not All Interactions Are Drug/Drug.... Some are Board/Pharmacist

*Melvin Rubin, P.D., Secretary and Commissioner
Maryland State Board of Pharmacy*

There are about 6,000 pharmacists licensed in Maryland, although not many more than half are active practicing pharmacists in the State. Retired pharmacists, pharmacists who were originally licensed in Maryland and now have moved out of state, and pharmacists working in other occupations usually keep their license active for some period of time.

Of the 3,000 or so who practice the profession, the overwhelming percentage have never come to the attention of the Board of Pharmacy related to a problem which could threaten their license -- and that's good. There are times when a pharmacist seeks information from the Board which requires interpretation of the laws and judgements from the Board Commissioners, and that's fine also. That leaves a small percentage of pharmacists who find themselves being examined by their Board for reasons that are maybe not so good.

This article deals with an explanation to the great majority of you who cross paths with the Board only for renewals, in order to show you the ways pharmacists or establishments licensed by the Board become involved in some form of investigation.

Whenever a citizen files a written complaint against a pharmacist or pharmacy the Board must investigate and report the results to the complainant. Most of these cases are closed with a minimum of effort and without significant repercussions for the pharmacist. Unless the case has the appearance of needing rapid action, the Board reacts to the written complaint by sending a letter to the licensee asking for their side of the story. The letter mentions that they are not required by law to respond but that we are trying to see if the issue can be resolved without a formal hearing or informal meeting. If the Board feels it is necessary for the pharmacist to be brought in for a discussion, a subpoena can be issued.

Assuming that a response is received, a committee of the Board, including a consumer member, meets to triage our response. Has the licensee properly addressed the complaint and attempted to satisfy the patient and developed protocols to assure that the problem will not recur -- as in the case of a prescription error? Or do we need more information with which to make a judgement? Or is the possibility of disciplinary action necessary to explore?

Most responses from the licensee satisfies the committee and letters are sent to them and to the complainant explaining that we feel the problem has been resolved. However the complaint becomes a part of the file of the licensee. Should repeat complaints be received, the file can be re-opened.

Although the majority of cases are able to be closed at this point, if the small committee which reviews the complaint is either unsure of what action to take or is sure that action should be taken, the issue is put on the agenda at the next Board meeting. Often at that time it is deemed necessary to refer the case to the Board's pharmacy compliance officer for investigation. Involved parties are interviewed and evidence is sought. The Board then reviews the results of the investigation and either closes the case, provides informational letters, or charges the licensee with violation of one or more appropriate pharmacy law.

While consumer complaints usually are able to be satisfied relatively easily, the Board at times has to bring charges against a pharmacist who is accused of diversion of controlled substances, illegal dispensing, incompetence, or any of a number of other infractions described in Title 12-313 of the Maryland Pharmacy Act. The Board is also sent information from the courts about pharmacists who have been convicted of a felony.

While consumer complaints usually are able to be satisfied, the Board at times has to bring charges against a pharmacist

In addition, the Division of Drug Control brings cases to our attention for consideration, at times dealing with bad faith prescriptions written by physicians and filled by pharmacists when evidence points to the fact that they had reason to believe the prescriptions were "bad" -- corresponding liability.

We also receive information from the National Association of Boards of Pharmacy clearing house regarding pharmacists who violate laws in other states.

Once charges are voted and the licensee notified, a hearing is scheduled. The registrant is given the opportunity to have a pre-hearing conference prior to a full Board hearing, usually attended by the licensee and their attorney, a pharmacist and consumer member of the Board, along with the Assistant Attorney General assigned to us and/or the Board's Executive Director. Often a consent agreement is worked out

with the licensee in which they agree to do or not do certain things. If the full Board agrees with the preliminary decision, it is signed, then monitored through the life of the agreement. For example, pharmacists who have been found to have taken illegal drugs may have their license suspended for a period of time, may receive a fine, or may have their license revoked. They may be required to attend Narcotics Anonymous or Alcoholics Anonymous meetings, have random urine tests, be monitored by the Pharmacy Rehabilitation Committee, take ethics courses and/or law courses. Some combination of these and other requirements are designed to assure the Board of the licensee's readiness to resume practice at some point in time.

Often the person is "stepped" back to having their license returned with no restrictions. Perhaps we would allow them to work in a non-dispensing role for some period of time, or only with another pharmacist. A last step would be to allow dispensing but have the person remain on probation.

As harsh as these requirements may seem, they are intended to bring the pharmacist back to the mainstream in a way that hopefully will assure that there is no re-occurrence of the problem.

If the licensee does not agree to a consent agreement at the pre-hearing conference, he or she has the right to have a hearing in front of the Board -- defense and prosecuting attorneys, court reporter, swearing in witnesses, expert witnesses -- a real courtroom scene. The Board of Pharmacy hears the testimony, if necessary over a two day period, then decides on the case. There is a right to appeal the case to the courts if desired.

There are many other reasons why someone comes to the attention of the Board -- falsifying an application (as in reporting continuing education credits which do not exist) -- has become too prevalent.

There are even other possibilities for information gathering -- as in an informal meeting. But the best part is that most of you will never have to find out how you will be treated by the Board of Pharmacy.

The Board has as its primary purpose the protection of the citizens of the State. Licensing and re-licensing pharmacists and establishments enables us to carry out this responsibility. We are glad to answer questions pharmacists have -- formally or informally, to issue your licenses, and say hello when we see you away from the Board office. It would be nice if there were no other reasons for pharmacists to have contact with the Board of Pharmacy.

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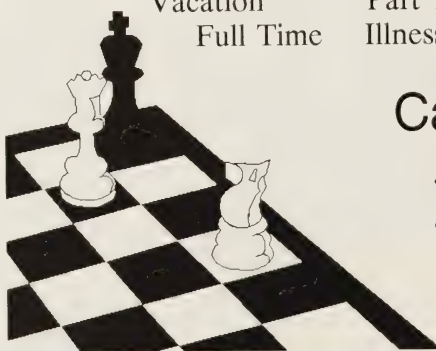
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Litigation Update

Those Who Fail to Learn From Their Mistakes...

The Court of Appeals of Missouri has recently reported a case in which a judge was ordered to permit a plaintiff's lawyer to have access to a pharmacy company's records of past lawsuits in which there are allegations of pharmacist professional liability.

The case reported that two children died at birth, allegedly as the result of their mother having been mistakenly dispensed Ritalin instead of the Ritrodine that had been prescribed. The parents of the children sued the pharmacy that dispensed the incorrect medication. The parents alleged that the company should be liable for failing to establish and maintain proper protocols and procedures to insure that appropriate medications are dispensed to patients.

The plaintiff sought to discover information about earlier lawsuits relating to the operation of the company's pharmacies for the three year period preceding the incident in question. The company opposed this attempt at discovery. The trial court refused and the plaintiff appealed.

The appellate court disagreed with the trial court. The court said that to prove that the company's protocols and procedures were inadequate, it would be highly relevant that other claims had been made because of misfilled prescriptions. The discovery sought by the plaintiff, according to the court, was viewed as a promising source of evidence that the company either knew or should have known that its system of processing prescription orders was faulty. Thus, the company was ordered to produce the information for the plaintiff, although there is still a question of whether that information will be ruled admissible in a court of law.

This case raises the interesting issue of whether it is possible to develop safer systems of processing prescription orders based on what has been learned

from past experience with problems in prescription processing. The plaintiff's argument would perhaps be that the failure to develop safer systems, or that the failure to use safer systems that are already developed, is negligence that could lead to liability of the company.

Of course, the company can be held liable for the mistake of its employee pharmacist. And that is traditionally how dispensing error cases have been characterized by plaintiff's lawyers; as isolated incidents of inattentiveness or inadvertence.



David B. Brushwood

This case is different because it questions not only the isolated incident of alleged negligence, but a systematic failure to learn from past mistakes. Isolated incidents can be understood (although perhaps not forgiven) as the inevitable result of human frailty. It is not possible to improve the human condition to a state of perfection, because humans are necessarily imperfect and capable of error. Human error is a part of living. This we understand and accept. Yet the failure to learn from past errors, and to

improve so as to avoid similar errors in the future, is more difficult to understand and accept.

This case does not say it is negligence to fail to examine legal claims and improve a drug distribution system based on lessons learned from those claims. That issue has yet to be fully litigated. This case does say that pharmacy companies with a history of litigation may have to provide the records of that litigation to a patient's lawyer in a lawsuit alleging poor dispensing procedures. As a result, community pharmacists should systematically review legal claims of negligence and change the system of drug distribution to reduce the likelihood of errors reoccurring.

Based on: *State ex re. Stolla v. Ely*, 1994 Westlaw 160195 (Mo. App May 3, 1994), © 1994. All Rights Reserved.

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Finding the Right Balance

The MPhA Mid-Year Meeting

February 26, 1995

Loews Annapolis Hotel, Annapolis

Program

8:00 - 8:45 am Registration and Continental Breakfast

8:45 - 9:00 am *Breakfast & Welcome*
Arnold Davidov, P.D., MPhA
President

9:00 - 10:30 am *How Easy Is It With —
"Pharmaceutical Liability"*
Continuing Education Seminar
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Gerald A. Mazzucca
Philadelphia Association of Retail Druggists
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Recent court decisions against pharmacists have had significant impact on professional liability. This program will review these liability issues and examine how expanded pharmaceutical care responsibilities will affect you.

10:30 - 12:30 *New Drugs and Therapies I*
Continuing Education Seminar
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David S. Roffman, Pharm.D.
Robert A. Kerr, Pharm.D.
University of Maryland School of Pharmacy

It's almost impossible to keep up with all the new drugs and therapies available. That's why this annual review is a must for every practitioner -- regardless of practice setting.

12:30 - 1:30 Buffet Luncheon
Atrium and Windjammer

1:30 - 2:30 *Presentations by
Board of Pharmacy
Nominees*
Professionwide Business Session
Chesapeake Ballroom
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2:30 - 4:00 *New Drugs and Therapies II*
Continuing Education Seminar
Chesapeake Ballroom

4:00 - 5:00 pm *MPhA History of Pharmacy
Roundtable Session*
Chesapeake Ballroom
Speaker Joseph Marrocco presiding

*Turn the page for
complete registration
information...*

Education Information



The Maryland Pharmacy Continuing Education Coordinating Council is approved by the American Council on Pharmaceutical Education as a provider of continuing education for pharmacists. The 1995 MPhA Mid-Year Educational Meeting will

provide attendees with 5 hours (0.5 CEU) of continuing education credit. Certificates will be available for pick-up at the conclusion of the seminar for pre-registrants only. Late and on-site registrants will receive their certificates by mail within 14 days of the seminar. **ACPE # 186-144-95-001, 186-144-95-002.**

Refund Policy

Cancellation refunds will be made upon request, minus a \$5 handling charge, if registration is canceled at least 72 hours before the seminar. All refunds will be processed after the seminar.

Meal Requests

Requests for special meals (kosher, vegetarian, etc.) must be made at the time of advance registration or no later than February 15, 1995.

Registration

Registration is \$50 for MPhA members (\$60 for non-members) if registration is postmarked before February 1, 1995. Registration received after February 1, 1995 and on-site will be \$60 for members (\$70 for non-members). To register for the Mid-Year Meeting, complete and detach the accompanying registration form. Return the form with payment (check or money order) to the MPhA offices. For further information or questions, contact MPhA at (410) 727-0746 or (800) 833-7587.

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The MPhA Mid-Year Meeting is made possible through the generous sponsorship of the following companies: Astra/Merck, Searle, SmithKline Beecham, Miles, Pfizer, Schering, Ortho Pharmaceuticals, Apoteco.

Directions

The Loews Annapolis Hotel is located at 126 West Street in Annapolis. From Baltimore: From I-695, take I-97 south to the merge onto Route 50 east. Take the Route 70 (Rowe Boulevard) exit into Annapolis. Bear right at the Treasury building and proceed through two lights to West Street. Turn right. The hotel is about one block north on the right hand side. From Washington: From I-95, take Route 50 east to Annapolis. Follow the directions above. A map is available from the MPhA offices.

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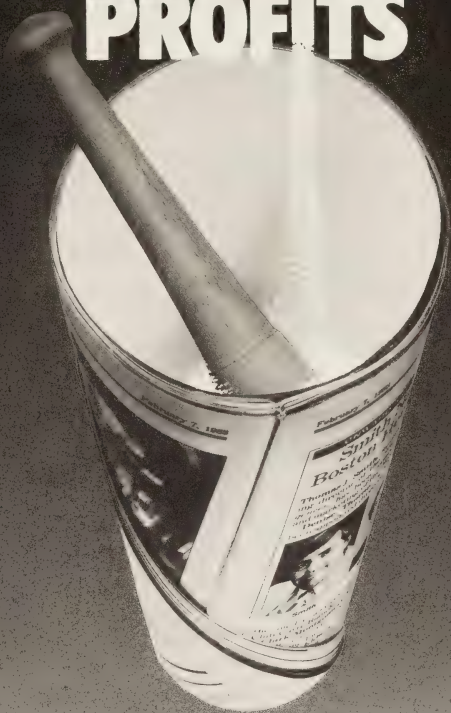
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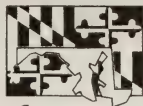


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Continuing Education

This lesson presents information on rimantadine (Flumadine), granisetron (Kytril) and cisapride (Propulsid). Dosage forms and regimens for these drugs are listed in Table 1.

As explained in Part I of this series, the "1P" designation noted after the name of the drug signifies that it was given priority approval by FDA because the drug represented a significant advantage over previously available therapy. The "1S" notation means the drug went through the standard approval process.

Antiviral Agent

Rimantadine (1P)
Trade name: *Flumadine*

Rimantadine (Flumadine) joins amantadine (Symmetrel) as therapy for the prevention and treatment of Influenza Type A infections. There are two major types of influenza viruses - Type A and Type B. Influenza Type A is more prevalent than Type B and causes more severe problems. It reportedly affects 12 to 50 million Americans and causes approximately 20,000 deaths each year. About 90 percent of the deaths are elderly patients.

The term Influenza Type A virus actually refers to a group of viruses that are at the same time both similar and different. To better understand this, a quick review of viruses will be helpful.

New Drug Review: Antiviral and Gastrointestinal Agents

J. Richard Wuest, R. Ph., Pharm.D.
Professor of Pharmacy Practice, University of Cincinnati

Thomas A. Gossel, R. Ph., Ph.D., Interim Dean
Ohio Northern University

A professional development program made possible by an educational grant from **SEARLE**.

What is a Virus?

A virus is a free-floating strand of DNA or RNA which contains the road map for reproduction. However, a virus is a single strand configuration rather than a double stranded helix as seen in the genes of cells that can replicate on their own. This means that viruses are not really "alive." They can only replicate within living (host) cells by using the substance of that cell for transcription, translation, replication and reproduction.

Viral DNA/RNA is contained within layers of proteins and lipids called a capsid envelope. As such, the virus is inactive (latent). Protruding out of the capsid are protein-based structures called "spikes."

When these spikes come in contact with receptive chemical structures on living cells (receptors), the virus binds to the receptor and stimulates the process whereby the cell engulfs the virus and brings it inside the host cell's cytoplasm. Once inside the host cell, the virus discards its capsid (un-coats) to release its DNA/RNA. This, in turn, enters the host cell's nucleus. Due to the small size and simple nature of viral DNA/RNA compared to the elaborate and cumbersome genome/chromosome/gene structure of the host cell, the virus can replicate approximately 20,000 times faster.

Therefore, the virus takes over the genetic coding of the host cell, uses the substance of the cell to replicate and create its clones, uses the host cell's membrane to form its capsid and releases its progeny to look for other cells to attack and destroy.

Overwhelmingly, most viruses are nonpathogenic. For many of those that do cause disease, science has determined the chemical configuration of their binding spikes (i.e., antigens), and vaccines have been developed to protect humans (and animals).

With the influenza viruses, specifically Influenza Type A virus which is the most virulent, the problem is that its RNA core consists of eight separate strands. Therefore, it can rearrange these strands (mutate) and change the configuration of its antigenic spikes (antigenic shift). This shift occurs nearly every year with a massive shift (flu epidemic) approximately every 17 to 20 years.

This renders the mutant strain immune to the previous year's vaccine.

Fortunately for those who live in the northern half of the Western Hemisphere, these mutations usually occur in Asia or South America (e.g., Beijing flu, Hong Kong flu, Asian Flu, Shanghai flu, Swine flu, Panama flu, etc.). Therefore, each year a vaccine can be prepared that is reasonably effective in preventing inoculated persons from catching the flu.

Impact of Influenza Infections

Most cases of acute influenza infections are debilitating but temporary, resolving in 7 to 14 days. However, two major complications can develop in patients -- viral pneumonia and bacterial pneumonia. These complications can cause morbidity in susceptible patients.

The impact of influenza on society can be seen in school and work absenteeism, increased visits to emergency room and increased hospital admissions for treatment of pneumonia. The mortality rate for those who develop pneumonia has been reported to be as high as 30 percent.

Those at highest risk of hospitalization and fatal outcomes are the elderly, especially those in

nursing homes; patients with chronic obstructive pulmonary disease, cardiovascular or renal disease, or diabetes; and , children with asthma. The most susceptible patents are those with HIV infections since the influenza virus can be devastating for them.

Therapeutics

Amantadine and rimantadine reduce the occurrence and severity of Influenza Type A infections. They are best used as an adjunct to flu vaccine which remains the treatment of choice for prevention of flu.

Since amantadine has been approved for preventing and treating Influenza Type A infections since 1966, more information is available on its effectiveness. The drug has been reported to be effective against Influenza Type A infections at a range of 70 to 90 percent.

In spite of its effectiveness, amantadine has been used very little, presumably because of the adverse reactions, particularly CNS side effects, seen in the target, elderly population. These side effects include nervousness, light-headedness, difficulty in concentration, insomnia, fatigue, and loss of appetite which have been reported in 5 to 33 percent of patients. Six to 16 percent of patients discontinue the drug because of these side effects.

Rimantadine, which has been available in Europe since 1991, and the former Soviet Union since 1988, is a slight chemical modification of amantadine. It is reportedly as effective as amantadine for its approved indications, but caused fewer CNS and anti

New Antiviral and Gastrointestinal Drugs

| Generic | Trade | Availability | Dosage Regimen |
|-------------|-----------|-----------------------------------|---|
| Rimantadine | Flumadine | 100mg tablets 50 mg/5 ml syrup | 100 mg BID |
| Granisetron | Kytril | 1 mg vials | 10 mcg/Kg by I.V. infusion over 5 minutes |
| Cisapride | Propulsid | 10 & 20 mg tablets | 10-20 mg QID 15 minutes before meals |

Table 1

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Patient Information for Flumadine

Flumadine is used to prevent or treat symptoms of influenza (flu) infections.

- Take Flumadine with a full glass of water. If it upsets your stomach, you may take it with food.
- If you are taking the liquid form, there are special measuring devices available. If you want one, ask one of our pharmacists.

To treat flu symptoms, it is best to start Flumadine as soon as possible after experiencing flu-like symptoms.

- While the occurrence is rare, some patients experience dizziness, blurred vision or drowsiness while taking Flumadine. If you do, be careful driving or performing hazardous tasks. Alcoholic beverages can increase the drowsiness.

- Do not take nonprescription analgesics (pain relievers) while taking Flumadine without checking with your doctor.

- It is important that you take Flumadine exactly as your doctor has instructed. Do not skip a dose, change the amount, or stop taking it without consulting your doctor.

- If your mouth becomes dry, you may suck on hard candy, chew gum or use a saliva substitute.

- If you miss a dose of Flumadine, take it as soon as possible. But, if it is almost time for your next dose, skip the missed dose and go back to your regular dosage schedule. Do not take a double dose, unless directed by your doctor.

- Do not keep or use outdated medicine.

- Keep this medicine at room temperature, in its original, labeled container and out of the reach of children.

- In case of accidental ingestion or overdose, call your doctor or poison control center immediately.

cholinergic side effects, nearly similar to those seen in the placebo treated group. Originally the property of DuPont Labs, Forest Labs has obtained the marketing rights to flumadine in the U.S.

The mechanism of action of rimantadine has not been fully determined, but the preponderance of evidence suggests that it interferes with viral un-coating. As stated earlier, in order for a virus to replicate in the host cell it has attacked, it must shed its capsid envelope and enter the cell's nucleus.

Rimantadine is thought to interfere with the process whereby the protein structure of the capsid liberates transcription-active viral RNA for transport to the nucleus. Instead, the protein-RNA complex is trapped in the cell's cytoplasm where it is incapable of initiating replication and will be destroyed eventually.

Side Effects and Dosage Regimen

Rimantadine in doses of 200 mg or higher causes nausea, dizziness, dry mouth and other CNS and anticholinergic side effects at the 5 percent and higher level. However, when given in doses of 100 mg, no side effects were seen above the 2 percent level. It has been reported that fewer than 5 percent of patients treated with 100 mg experienced any side effects. Interestingly, over 19 percent of patients receiving a placebo complained of annoying adverse reactions.

Flumadine is available as a 100 mg film-coated tablet and 50 mg/5 ml raspberry flavored syrup. The recommended dose for prophylaxis is 100 mg twice a

day for the duration of influenza activity in the community, up to six weeks.

Candidates for therapy with rimantadine include those who can not tolerate or are allergic to the flu vaccine, those who did not get vaccinated and are now exposed, high risk patients, and vaccinated patients during the two weeks that it takes for the vaccine to stimulate sufficient antibody production.

For treatment of an infection, the recommended dose is 100 mg twice daily for seven days from the initial onset of symptoms, i.e., fever, chills, headache, muscle pain, sore throat and cough. The drug should be started at the earliest signs and symptoms of influenza infections during an outbreak in the community. In both instances, the dose for elderly patients and those with liver or renal dysfunction is 100 mg daily.

Gastrointestinal Agents

Granisetron (1S)

Trade Name: Kytril



granisetron is an antiemetic agent.

To review, nausea and vomiting are complex mechanisms

by which the body rids itself of gastric contents.

Two major areas in the brainstem are responsible of emesis: the chemoreceptor trigger zone (CTZ) and the vomiting center (VC). Upon reaching its threshold for firing, the VC initiates strong contractions of the diaphragm and abdominal muscles to propel stomach contents upward and outward. The VC is stimulated by impulses generated from

Table 2

the CTZ. Nausea is the experience one has prior to vomiting, and it can be lessened or prevented by inhibiting the CTZ.

Nausea and vomiting have many causes. They can be physiologic due to excessive tension in and irritation of the esophagus, stomach or duodenum. They result from an imbalance in hemostasis in the body as seen in many diseases. Nausea and vomiting are caused by direct stimulation of the CTZ by drugs; psychologically by unpleasant sights, smells, thoughts, etc.; or result from disturbances in the vestibular apparatus as seen in motion sickness.

A number of chemical neurotransmitters have been identified as part of the CTZ/VC complex. They include acetylcholine, dopamine, enkephalins, gamma-aminobutyric acid, glutamine, norepinephrine and serotonin.

The neurotransmitters that predominated in causing nausea and vomiting appear to be acetylcholine, dopamine, and serotonin. This can be seen with the agents used to treat nausea and vomiting. The anticholinergics (antihistamines) are most successful for treating motion sickness. The agents of choice for many years in treating drug and disease related emesis were the dopamine antagonists. Originally these were the phenothiazines, but more recently metoclopramide has been the agent of choice, since it causes fewer central effects than the former drugs.

When the first serotonin antagonist (ondansetron-Zofran) became available for treating chemotherapy-induced nausea and vomiting, it quickly became

the agent of choice. Chemotherapeutic agents are very emetogenic. This is largely due to the increased number of serotonin (5HT) receptors. Agents that block these specific receptors control drug-induced nausea and vomiting without significantly affecting the cardiovascular and central nervous systems.

Granisetron (Kytril) is a serotonin (5HT₃) antagonist. It exerts its antiemetic activity by preventing serotonin, released in response to toxins including cancer drugs, from stimulating the CTZ and VC. Two other members of the group, dolasetron and tropisetron, are currently in clinical trials.

The drug is approved for prevention of nausea and vomiting associated with emetogenic cancer therapy, including high-dose cisplatin. The 5HT₃ antagonists plus corticosteroids at medium doses (most specifically dexamethasone) appear to be superior to the previous treatment of choice: metoclopramide and dexamethasone. The addition of the corticosteroid allows a lower dose of the 5HT₃ antagonist without loss of antiemetic activity.

Ondansetron led the way as an antiemetic without the extrapyramidal effects seen with metoclopramide. Unlike metoclopramide, the 5HT₃ antagonists have no apparent action on dopamine receptors. This latter

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action of metoclopramide, is what causes extrapyramidal symptoms and sedation.

Ondansetron has an additional indication for treating post-surgical emesis. Other indications are anticipated for the group. The most frequently reported side effect from granisetron is headache (11 to 16 percent), followed by constipation at 4 percent. Other adverse reactions reported, rarely, are somnolence, dizziness, diarrhea and flushing.

Granisetron has been available in 30 countries and used to treat over 2.5 million episodes of chemotherapeutic and radiation-induced emesis before release in the U.S. An oral dosage form is available elsewhere in the world.

Kytril is marketed in a 1 mg single dose vial which is to be diluted in normal saline or D5W to a total volume of 20 to 50 ml. The 1 mg will handle up to a 220 pound patient for one course of therapy. It is administered in a single dose of 10 mcg/Kg by I.V. infusion over approximately 5 minutes, beginning 30 minutes before chemotherapy is initiated, and only on the day(s) chemotherapy is given.

Cisapride (1P)

Trade Name: Propulsid

Cisapride is referred to as a prokinetic agent. This means that it restores and facilitates motility in the gastrointestinal tract (GIT). Upper GIT motility is controlled by an interplay between dopamine and acetylcholine. Dopamine inhibits and acetylcholine stimulates it. Therefore, drugs that block dopamine (i.e., metoclopramide) increase GIT motility

as do drugs that increase acetylcholine activity (i.e., cisapride). The prokinetic agents are used to treat gastroesophageal reflux disease (GERD).

Cisapride increases physiological release of acetylcholine from the post-ganglionic nerve endings of the neurons controlling the gastrointestinal system. This improves the propulsive motor activity of the esophagus and stomach.

Another drug that affects gastric motility by inhibiting dopamine receptors in the GIT that is useful in treating gastric reflux disorders is metoclopramide. However, this drug also blocks dopamine receptors in the brain and can cause Parkinson-like symptoms including tremors and agitation in 10 to 20 percent of patients.



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The third drug in the prokinetic category is domperidone which is not commercially available in the U.S. It is a peripherally acting dopamine inhibitor which enhances motility in the esophagus, stomach and small intestine. It does not cause CNS effects as does metoclopramide.

GERD can result from a combination of several factors including reduced esophageal sphincter tone which allows reflux of gastric contents into the esophagus, over time, its mucosa is damaged due to the prolonged lowered pH. GERD is manifested mainly as heartburn and regurgitation. Other symptoms are nausea, vomiting and post-meal abdominal discomfort.



here are several types of GERD. the initial indication for cisapride is nocturnal

GERD. As the name implies, this condition occurs after the evening meal, often after lying down. It is primarily a motility disorder. Hypersecretion of gastric acid is not always a predisposing factor, so antacids, histamine-2 blockers and omeprazole may not be candidates for therapy in all patients with GERD.

Cisapride is effective for this indication because it increases the lower esophageal sphincter (LES) pressure which reestablishes the esophageal barrier to reflux acid. It increases peristaltic activity in the esophagus which increases the clearance of acidic fluids that have been regurgitated. It also speeds gastric emptying time which decreases the back pressure of gastric contents against the LES and into the esophagus.

Cisapride is being studied for a number of other GIT disorders including constipation. While not approved for this indication, cisapride has been shown in a few studies to restore colonic propulsive activity in some patients with chronic constipation resulting from nonorganic (i.e., not caused by physical disease) causes and laxative abuse.

Preliminary evidence suggests that 5 to 10 mg TID or 20 mg BID for 8 to 12 weeks progressively increases the frequency of bowel movements. The greatest effect seems to be in patients with atonic colon due to laxative abuse. However, there are no studies comparing cisapride to a high fiber diet for this use.

There are relatively few side effects reported for cisapride with headache (19 versus 17 percent in the placebo group), diarrhea (14 vs 10 percent), nausea (8 vs 8 percent), constipation (7 vs 3 percent) and rhinitis (7 vs 6 percent) being the only adverse effects over the 5 percent level. As can be seen by comparing cisapride to placebo, these are not overly significant. It is of interest that cisapride is used to treat constipation in some patients, and it can cause constipation in others.

Important information that should be given to the patient is that the dosage is best taken 15 minutes before a meal or snack. The presence of food in the stomach increases cisapride absorption and efficiency significantly. Other information that can be used in counseling patients receiving Propulsid is listed in Table 3.

Patient Information for Propulsid

Propulsid is used to relieve nighttime heartburn associated with GERD (gastroesophageal reflux disease) and other conditions as determined by your doctor.

- Propulsid should be taken with a glass of water at least 15 minutes before meals or snacks, unless directed otherwise by your doctor.
- While Propulsid does not cause drowsiness on its own, it can enhance the drowsiness and sedation caused by other depressants such as alcohol and sleeping medicines.
- It is important that you take Propulsid exactly as your doctor has instructed. *Do not* skip a dose, change the amount, or stop taking it without consulting your doctor.
- If you miss a dose of Propulsid, take it as soon as possible. but, if it is almost time for your next dose, skip the missed dose and go back to your regular dose. *Do not* take a double dose, unless directed by your doctor.
- *Do not* keep or use outdated medicine.
- Keep this medicine at room temperature, in its original, labeled container and out of the reach of children.
- In case of accidental ingestion or overdose, call your doctor or poison control center immediately.

Every medicine is capable of producing side effects. Most patients experience little or no problems while taking Propulsid. However, be sure to tell your doctor if the following occur: severe headache, diarrhea, abdominal pain, runny nose, or any other unusual, bothersome effects.

Adapted from the Pharmex PALs (patient advisory leaflets). For more information, call 1-800-233-0585.

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Maryland Pharmacists

The Entrepreneurs

This Month
Doug Campbell, Pharmacist
The Medicine Shoppe, Towson, Maryland

Doug Campbell knew he had a problem. The ache in his jaw was getting worse every hour. Soon, the pain became unbearable. Doug did what most of us would have done -- he made an appointment to see the family physician. After prescribing an antibiotic for the infection, he sent Doug to a specialist to pinpoint which gland was infected. The specialist told Doug that the gland would have to be surgically removed within the next two days or Doug would have a much bigger problem.

But Dr. Campbell did *not* schedule the surgery. Once the troubled gland was verified, his family physician prescribed a homeopathic remedy for the problem. Within two days, instead of having surgery, Doug was fully recovered. That episode was two years ago and the gland has never bothered him since.

It should come as no surprise to anyone who knows him that Doug's family physician is a homeopath. Doug has one of the larger inventories of homeopathic medicines in Maryland. His is

active in two homeopathic trade organizations -- the American Homeopathic Association and the American Association of Homeopathic Pharmacists.

The store is located in the Drumcastle Shopping Center on York Road in Towson, Maryland. When Doug opened his Medicine Shoppe in 1981, his pharmacy was one of the first in the state to offer homeopathic remedies.

When most of us think about a pharmacy selling homeopathic remedies, we think of a store carrying a few products, such as oscillococcinum for flu relief, and perhaps a sinusitis tablet (did you know that oscillococcinum is made homeopathically from the heart and liver of a duck? Preparing a product homeopathically means putting it through a dilution process by the standards set by the profession).

The Towson Medicine Shoppe carries not just those products, but the entire line of single and multiple remedies. Doug also sells and counsels his patients about the *nineteen* other lines of homeopathic products and herbal medications. His technicians average five years in experience working with Doug's homeopathic products, so they can provide assistance to patients also.

"Pharmacists tend to think about homeopathic products as being only over-the-counter medications. Few are aware that there are prescription homeopathic preparations also, and that they are covered by most major prescription cards," says Doug. That third-party coverage is due in large part to Doug's hard work!

Doug sold her more than a remedy for her problem that day. From now on, when she has a self-limiting medical problem she won't be going to the nearest mass-merchandising outlet to buy what the man on TV told her to buy. She'll be visiting Doug Campbell's Medicine Shoppe! **MP**

Currently, there are only two homeopathic physicians practicing in the Baltimore area. These are doctors who have graduated from medical school and then specialized in homeopathic medicine. They are kept very busy by Doug's patient referrals. A new patient can expect to wait up to six months for an appointment. The backlog should be easing soon, thanks to an accredited course at the University of Maryland where physicians can obtain training in this fascinating field. By the end of 1995, there should be an additional 200 homeopathic physicians trained in the United States. (Did you know there are also currently six homeopathic veterinarians in Maryland?)

Doug says "about 50 percent of my business comes from non-allopathic medications." But don't be fooled by this impressive statistic. Selling these products is not as easy as ordered from a supply catalog. "There are volumes of information to be digested before you can effectively counsel a patient about a remedy. A good homeopathic pharmacist will not treat anything other than a self-limiting condition.... all other conditions are referred to a homeopathic physician."

While Doug was being profiled for this article, a young mother came in to seek a specific remedy. She was breastfeeding and was concerned about the drug showing up in her milk. Doug handled the question with complete confidence. He spent about five minutes discussing various therapeutic alternatives, both herbal and homeopathic.



This article is the first in a series profiling our state's entrepreneurial pharmacists. If you have a pharmacist to profile, call the MPPh offices at (800) 833-7587.

Continuing Education Quiz

January 1995 -- Antivirals/GI Products

This month's questions are taken from the article on recently introduced drug therapies for antivirals and other products that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members \$5.00). The completed quiz for this issue must be received by June 30, 1995. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name _____

Address _____

City/State/ZIP Code _____

1. Rimantadine is most similar chemically and therapeutically to:
 - a. ranitidine
 - b. Reglan
 - c. rifampin
 - d. Symmetrel
2. Kytiril exerts its antiemetic activity by antagonizing:
 - a. acetylcholine
 - b. dopamine
 - c. histamine
 - d. serotonin
3. Patients receiving Propulsid should be advised to take the tablets:
 - a. one hour after meals on an empty stomach
 - b. fifteen minutes before meals or a snack
 - c. two hours before bedtime
 - d. as soon as possible in the morning
4. Which of the following is a true statement concerning viruses?
 - a. They mutate their antigen spikes.
 - b. They replicate outside of living cells.
 - c. They are double stranded DNA helixes.
 - d. They are all pathogenic to humans.
5. Propulsid is classified as a(an):
 - a. antiemetic
 - b. prokinetic agent
 - c. antisecretory agent
 - d. laxative
6. Propulsid exerts its therapeutic effect by increasing the activity of:
 - a. acetylcholine
 - b. dopamine
 - c. histamine
 - d. serotonin
7. The major complication to acute influenza infection is:
 - a. asthma
 - b. hepatitis
 - c. pneumonia
 - d. shingles
8. Granisetron is most similar chemically and therapeutically to:
 - a. Antivert
 - b. Imitrex
 - c. Reglan
 - d. Zofran
9. The most frequently reported side effect of Kytiril is:
 - a. drowsiness
 - b. headache
 - c. insomnia
 - d. nausea
10. Which of the following most accurately explains the advantage of flumadine over other similar antivirals?
 - a. It has greater ability to penetrate human cells.
 - b. It causes less cross-sensitivity for patients allergic to flu vaccine.
 - c. It has fewer CNS and anticholinergic side effects.
 - d. It is more effective with a much shorter course of therapy.

CLASSIFIED ADS

Positions

PHARMACISTS Earn extra money working around your schedule. Seeking retail, hospital, and institutional pharmacists for prn employment. Enjoy flexibility, an excellent pay rate, and cash bonuses. Join *PharmaSTAT!* For information call (410) 659-STAT.

PHARMACIST WANTED. Due to recent expansion, Revco is actively seeking full-time and part-time pharmacists in various locations thru out Maryland. We offer a complete benefit package including medical, dental, life and disability insurance, profit sharing, Rx bonus and continuing education. Our computer system is state-of-the-art. Call Brian Chivers at (301) 893-3704.

PHARMACISTS/MANAGERS WANTED Thrift/Treasury Drug, a subsidiary of JC Penney Company, a Fortune 100 company, has career opportunities available in the Cumberland, MD area for staff pharmacists and pharmacists looking for a chance to enter into the Pharmacy Management field. These positions feature: excellent starting salary (with bonus for management), comprehensive benefit package including dental, profit sharing, and a 5-day workweek with every other weekend off. Contact Bill Kerrish at (800) 284-7438, extension 8374.

PART TIME PHARMACIST available. 15-20 hours/week. Experienced in all phases of community pharmacy. 3 PM computer experience. Call (410) 484-5527.

PHARMACIST AVAILABLE for part-time or full-time work. Call (410) 363-3699.

Services

20% DISCOUNT on awards, plaques, trophies, and engraving to MPhA members. Call Rudy Winternitz, P.D. at Washington Trophy Center, (202) 966-1255.

PHARMACISTS REHABILITATION COMMITTEE For private, confidential referrals call (410) 727-0746 or (410) 706-7513.

Rx LICENSE TAGS are still available! A special benefit "for members only" that costs only a nominal fee. If interested, call Mary Ann at the MPhA offices toll-free, (800) 833-7587.

Miscellaneous

WANTED Baltimore pharmacy artifacts and objects (especially local pharmaceuticals, advertising posters and counter top displays) for Baltimore Museum of Industry. Call (410) 727-4808, extension 4.

Business Opportunities

INFUSION BILLING SPECIALIST. Inexperienced Billers + Employee Turn Over = \$\$ Problems. We are "the" experts in problem reimbursement. Over 12 years experience in billing with 8 years in the infusion field. We take the hassles out of reimbursement. Call now for prompt, professional billing service. Call (410) 391-1903 or 426-8711.

PHARMACY FOR SALE located in a medical building. Good location with parking. Medical supplies and surgical support stockings account for 65% annual income. This store has a lot of potential for the right person and it is priced for a quick sale, only \$175,000. Phone (301) 474-5151.

Vacation Ideas

OCEANFRONT OCEAN CITY CONDO Fully furnished 2 BR, 2 BA, cable TV, VCR, W/D, indoor pool, lighted tennis courts, sauna, gameroom. Convenient location, SeaWatch at 115th Street. Great off season rates. Call now for more information. (410) 647-6924.

SUMMER VACATION RENTAL in Wilwood Crest, NJ. Minutes from historic Cape May. 3 BR, 2 bath condo. Kitchen, dining room and living room. Includes full length deck overlooking Sunset Lake. Located 4 blocks from large, clean beach. Weekly rentals June thru September. Call for more information (410) 328-5668. Ask for Mike.

LUXURY CONDO FOR SALE in Canvasback Cove with boat slip and bubbler -- low \$100's. Attention investors! 3 BR, 2 BA TH in Highlandtown with seller assisted


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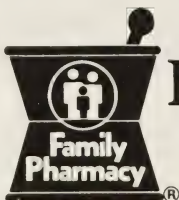
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NEWSLETTER

The Maryland Pharmacists Association

650 Lombard Street

Baltimore, Maryland 21201

(410) 727-0746

Free, Free, Free, Free

(We knew that would get your attention!)

Don't forget that as a member of MPhA, you can now take advantage of the one credit monthly continuing education articles in our journal *at no charge*. This is one additional benefit that the Board of Trustees has created to help you get real value from your dues.

As noted in the January issue, our journal is now being sent to all pharmacists in Maryland -- member and non-member alike. We are doing this to show non-members what our organization does and to bring them into the Association. This newsletter, however, is sent only to members.

If you have a non-member colleague, invite and encourage them to join. The benefits far outweigh the investment. The more members we have, the more things we can do!

Managed Care Grows

According to HHS Secretary Donna Shalala, Medicaid beneficiaries enrolled in managed care health plans jumped 62.5% during the past year. About 23% of the 34 million Medicaid beneficiaries in the US receive their medical care through some form of managed care system. That's a 14% increase from 1993 enrollments.

January 1995

The MPhA Newsletter is published monthly except during the months of July and August when the issues are combined. For information about any article contained herein, contact MPhA at (410) 727-0746 or toll-free at (800) 833-7587. President: Arnold Davidov, P.D.; Chairman, Board of Trustees: Howard Schiff, P.D.; Production Manager: David Miller, P.D..

This month's newsletter contains an insert from the University of Maryland School of Pharmacy. The views and contents this insert are those of the School. The insert is presented by MPhA as a means for its members to remain informed about the School's activities.

Board of Pharmacy Nominations

In 1992, the Maryland General Assembly changed the laws governing the appointment of pharmacists to the Maryland State Board of Pharmacy. The new laws now enable all pharmacists in the state to have the opportunity to nominate and vote for the person they feel would best represent their interests as a Board Commissioner.

Last fall, the Maryland Pharmacists Association began the lengthy process of obtaining nominations from individuals interested in serving on the Board of Pharmacy. A call for nominations was issued to pharmacists through the MPhA newsletter and by flyers. "I am pleased to announce that eight exceptional pharmacists have been nominated for the 1995 Board of Pharmacy elections," said MPhA Nominating Committee Chairman **Jim Tristani**. These pharmacists are: **Phyllis Bartilucci, Morris Delcher, E. Robert Feroli, Jr., Janet Getzy Hart, David Knauer, W. Irving Lottier, Raymond Morris, Jacob Raitt**.

Each of the nominees has been invited to speak at the 1995 MPhA Mid-Year Meeting on Sunday, February 26 at the Loews Annapolis Hotel. Written nominee statements will appear in the March 1995 *The Maryland Pharmacist*. That issue of the journal will also include a return envelope and ballot for each pharmacist in the state.



MPhA Given Major Educational Grant



Searle has accepted a grant proposal from MPhA to fund a statewide series of educational programs designed to teach pharmacists the basic elements of pharmacy services documentation, billing and reimbursement. These programs will be offered through local and state professional associations, chains pharmacies, and any other interested group of pharmacists.

President **Arnold Davidov** acknowledged the \$10,300 grant support at the January meeting of the Board of Trustees. "One of my major goals as President is to show pharmacists that it is not hard to document and bill for their services. I believe that our future does lie in being able to demonstrate the value we bring to the health care system. Searle's financial and professional commitment has made it possible for this organization to help MPhA bring that message to as many pharmacists as possible."

Fritz Berman Seminar Announced

The Kappa Chapter of the Alpha Zeta Omega Pharmaceutical Fraternity announced that the annual "Fritz Berman Memorial Seminar" will be held on Sunday, March 19, 1995 at the Holiday Inn, Pikesville.

"Our seminar this year is all about 'Body Plumbing'.... prostate cancer and disease and urinary incontinence," says MPhA's AZO Delegate **Dennis Klein**. "We are very fortunate to have Dr. Jeffery Chircus, a local urologist, as our speaker."



For more information about the seminar, look for the full-page advertisement in the February issue of *The Maryland Pharmacist*. Or, if you prefer, call AZO Seminar Planning **David Banks** at (410) 465-5683.

Third Party News

APS

Arnold Blaustein asks all pharmacists to update their records. Effective November 14, 1994 Associated Prescription Services is now located at 104 Church Lane, Suite 200, Baltimore, 21208. Their local phone number is (410) 602-3339 and their local FAX phone is (410) 602-3398. The toll-free number remains unchanged.

PCS

PCS Health Systems announced in late December that they are launching a new Workers Compensation reimbursement program in Maryland and other states. Offered through Champion International Corporation, the pilot program will be served through pharmacies participating in PCS' Managed Care Program (MCP). Recipients will have a paper drug card marked "Workers' Compensation Prescription Program" and listing the PCS carrier/group number. Reimbursement is the lower of:

- Usual and customary or
- AWP + 20% + \$3.75 (yes, that's *plus* 20%)

Also at the end of December, PCS announced that the cost reimbursement for their Maryland State Employees/Retirees Plan will change from AWP-8% to AWP-10%. This change is expected to save the state \$875,000.

Please note. Many pharmacists have called asking questions about the State Employees Plan. The plan still continues to be administered by PCS. There has been no change to the prescription benefit carrier. What has changed is the health insurance carriers offered to State Employees.

Maryland Medical/Pharmacy Assistance

Be advised that at the beginning of January, certain Merck products -- sold to Merck's Astra Division late in 1994 -- were still being paid at old Merck prices by the Maryland Medical and Pharmacy Assistance Programs. Astra changed prices and NDC numbers upon purchase of Plendil, Tonocard, and Prilosec. Look carefully at your reconciliation sheets to ensure that you are receiving proper payment for these products.

Don't Pay More

If you've been putting off registering for the upcoming 1995 MPhA Mid-Year Educational Program, you may end up costing yourself some cash! Early bird registration rates for the Mid-Year end on February 1.

The MPhA Mid-Year will be held on February 26, 1995 at the Loews Hotel in Annapolis. The 5 credit-hour program will feature a discussion of pharmacist liability and a review of new drugs and drug therapies introduced in 1994. Luncheon, continental breakfast, and snacks are included in the registration fee.

Registration forms and brochures were mailed to all members in December. An additional form also appears in the January *The Maryland Pharmacist*. If can't locate yours, just give us a call and we will be happy to send you another.

Don't forget. You can now charge your registration and dues to your VISA or MasterCard.

Scholarship Applications Requested

The MPhA Past Presidents Council is now accepting applications for the MPhA PEP Scholarships and the Harry Kaufman Award.



"MPhA created the PEP Scholarships to help strapped students meet some of their financial needs while they perform their externships," said Council Chairman **Nicholas Lykos**. "Any pharmacy student at the University of



Maryland may apply for the scholarships. In the past, we have given 2 to 3 scholarships ranging from \$300 to \$500 each year. These scholarships are the direct result of voluntary member contributions." Students are encouraged to call MPhA for a formal application. Deadline for applications is March 1, 1995. Nominations are also being sought for the Association's Harry Kaufman Award. This award, presented to a graduating senior, recognizes outstanding services to the community or pharmacy while a student. The award consists of a plaque and \$100 check. Forms for nomination are also available by calling MPhA at (800) 833-7587.

DUR Reviewers Needed

Mid-Atlantic DUR is seeking interested, committed pharmacists to serve as pharmacy services reviewers. Pharmacists are needed from Baltimore City, Baltimore, Howard, Montgomery, and Prince Georges Counties.

Reviewers must:

- Have a thorough working knowledge of current therapeutics.
- Work well in a committee setting.
- Attend scheduled monthly committee meetings.
- Keep up-to-date on current practice standards by virtue of continuing education or other means.

If interested, contact DUR Services Director Richard Baylis or DUR Assistant Donna Clatchey at (410) 727-6122.

School of Pharmacy News

University of Maryland at Baltimore

Maryland's School of Pharmacy for Over 150 Years

January 1995

Pharmacy School Faculty On the Cutting Edge in Pharmaceutical Research and Practice

With a major curricular revision of its professional program underway, you might think that research and practice initiatives have been put on the back burner. In fact, just the reverse is true. The faculty are currently immersed in major research initiatives in practically every area of pharmaceutical research and practice.

Stuart Speedie, Ken Loving and Steve Skarupa in the Pharmacy Practice and Science Department, and a team of researchers from the Food and Drug Administration (FDA) and University of Maryland Baltimore County (UMBC) have developed a new software system, dubbed ACCESS/OGD, that brings the FDA Office of Generic Drugs into the Electronic Age. Part of the three year \$7.1 million collaborative agreement between the FDA and the School, this database has the potential for electronic submissions of abbreviated new drug applications (ANDA) as well as strengthening the review process by making past submissions easily accessible to reviewers on line. Ralph Shangraw, co-principal investigator, developed and led the OGD training program for reviewers and other FDA personnel. In the November 1994 *FDA Review* OGD Acting Director Douglas L. Sporn credited this collaboration "for improved internal administrative procedures that reduced generic drug review time from 14 months in 1990 to four months now." Larry L. Augsburger, principal investigator for the collaborative agreement, led the research efforts with the establishment a Drug Development Facility with a GMP (Good Manufacturing Practices) laboratory which can run small batches and do scale-up with outside contractors. UMAB is one of only three schools of pharmacy in the country to have this capability. The research conducted under this contract, assesses the impact of formulation and process changes on bioavailability, and has contributed to a more efficient review process by expanding the scientific basis for decision making at the FDA.

In another collaborative effort, Pharmaceutical Sciences Department faculty, Alexander MacKerell, a computational chemist and principal

Continued on the next page

Dean's Colloquium: Exploring Pharmaceutical Care in Pharmacy Practice

The Dean's Colloquium offers a provocative series of lectures by academicians and scientists on the issues impacting on today's practice of pharmacy. These programs, which are free and open to the pharmacy community, are held throughout the school year, at 11 a.m., on Tuesdays. Call (410) 706-0565 for location. The Dean's Colloquia are funded by Glaxo, Inc., Marion Merrell Dow Inc., and the David Stewart Associates.

January 31

George E. Dukes, Jr., Pharm.D.
University of Maryland at Baltimore

Development of a Model for Determining Metabolic Function in Hepatic Disease

February 28

Earlene E. Lipowski, Ph.D.
University of Florida
Patient Satisfaction with Pharmaceutical Care

March 28

Heidi M. Anderson Harper, Ph.D.
Auburn University
Pilot Research Results: Patient Education Using the USP DI Visualized "About Your Diabetes."

April 11

Stanley M. Shaw, Ph.D.
Purdue University
Nuclear Pharmacy Practice PLUS Care



UNIVERSITY OF MARYLAND
AT BALTIMORE

The School of Pharmacy News is produced by the University of Maryland School of Pharmacy which is solely responsible for its content. It is published quarterly in the MPhA Newsletter as a service to MPhA members. If you have any questions or comments regarding the content of this insert, contact Jacquie Lucy, director of public affairs, (410) 706-5893.

Cutting Edge Research--continued from previous page

investigator for the grant, **James Polli**, a drug delivery systems specialist and **David Young**, a pharmacokineticist and director of the School's Pharmacokinetics/Biopharmaceutics Laboratory, are working on a grant from Procter & Gamble that will attempt to predict biological absorption and disposition of oral drugs based on their chemical structure. Ultimately, this could mean decreasing the number of animal studies needed for drug research and development and getting drugs to market more quickly and cost-effectively.

Emmeline Edwards is currently the only researcher in the country using rats as the animal model to explore the possibility of a genetic link to depression. Over a nine year period, Edwards has selectively bred rats to develop a strain with "learned helplessness," the behavioral deficit which characterizes clinical depression. Now in the 34th generation, she has been able to produce ten pairs per strain with no sibling mating that exhibit "learned helplessness," i.e., make no effort to escape an adverse situation when given the opportunity. This animal model could not only provide a scientific link to the genetic origin of depression but also serve as a potential screening tool for *in vivo* studies of depression. Dr. Edward's research was recently published in **Einstein Psychiatry Publication No.8**, *Genetic Studies of Affective Disorders* in the chapter *Animal Models in the Study of Genetic Factors in Human Psychopathy* by Fritz A. Henn and Emmeline Edwards.

Catherine Fields, Mona Gold, Diane McNally, Colleen Metge, Theresa Ng and Ilene Zuckerman, of the University of Maryland Center on Drugs and Public Policy, received a grant from the Maryland Department of Health and Mental Hygiene to bring pharmaceutical care into the ambulatory setting of four area hospitals--Johns Hopkins, St. Agnes, Sinai and University of Maryland Medical Center. This practice initiative is based on the assumption that pharmacists should be performing pharmaceutical care at the site of prescribing to reduce misprescribing by physicians and drug misuse and/or noncompliance by patients. Ideally, this program should lead to increased patient compliance resulting in improved patient outcomes and even lower drug costs. The Center also received a recent grant from a Health Care Finance Administration (HCFA) to conduct a study entitled "Identifying Drug Therapy Inappropriateness: Determining the Validity of Drug Use Review Screening Criteria." The goal of this research is to strengthen the ability of outpatient DUR screening to identify clinically significant cases of inappropriate drug prescribing in the Medicaid program. The project team includes **Ilene Zuckerman, David Knapp, Stuart Speedie, Colleen Metge** of the UMAB Pharmacy School as well as **Frank Hooper** of the UMAB School of Medicine.

Tony Tommasello and Trent Tschirgi in the Office of Substance Abuse Studies have invented a Hypertext Drug Information Database to create and maintain an on-line, referenced, rapid access computer information system on the effects of alcohol and other psychoactive substances. Their work has been published in *Drug Information Journal* 28:647-655 (94) in an article entitled *Computer-Automated Reprint Requests*.

Scientific exploration is alive and thriving at the School of Pharmacy!

Jacquie Lucy

Coming Events!!

March 9

1995 Peter P. Lamy Lecture

Gene Cohen, M.D., Ph.D.,
Former deputy director of the National
Institute on Aging,
*Creativity in Aging: Relevance to
Research, Practice and Policy.*
8:30 a.m. Westminster Hall
Reservations -- (410) 706-5893

March 19-25, 1995

National Poison Prevention Week

April 1

Open House for Prospective Professional Students

9 a.m. through 12 p.m.
Presentations/Tours of Pharmacy Hall
Preregistration --(410) 706-0756

April 18

1995 Andrew G. DuMez Memorial Lecture

Speaker TBA
11 a.m. Dean E. Leavitt Hall

Rho Chi Installation and Banquet

6 p.m., BWI Airport Marriott
Contact Dr. Myron Weiner at
(410) 706-2970 for details.

April 28

Special Symposium Honoring Ralph F. Shangraw, Ph.D.

8:30 a.m. - 5:00 p.m. Baltimore Omni
Hotel
Contact Jacquie Lucy at (410) 706-
5893 for details.

Alumni Association Monthly Meetings

January 24

February 28

March 28

April 25

The 4th Tuesday, 8:15 p.m.,
Rm. 740 Pharmacy Hall
Members welcomed!

Making Headlines

John Jordan, director of hospital pharmacy at the Baltimore Veterans Administration Medical Center recently graduated from the SmithKline Beecham Executive Management Program. He was one of 37 to participate in an innovative program designed to help hospital pharmacy directors improve their management skills.

Debra Weintraub, pharmacy manager at Suburban Hospital in Bethesda, has been selected as the first ever recipient of the American



Pharmaceutical Association's APPM Distinguished Achievement Award in Institutional Practice. This new award, sponsored by Wyeth-Ayerst, recognizes the accomplishments of an individual who has made a significant or sustained contribution to the provision of pharmaceutical care within the practice areas represented by the APhA-APPM Section on Institutional Practice.

Tracy Baroni is the Board of Pharmacy's new Pharmacy Compliance Officer. She graduated from Duquesne School of Pharmacy in 1987 and received her law degree from the University of Baltimore in 1993. She brings to the position more than three years of community practice and four years of institutional practice experience.

Leslie Epstein, vice president at Advance Paradigm, was featured in the November/December 1994 issue of *Managed Care Pharmacy Practice* magazine. She has also been named as a consultant member of the Corbett Managed Health Care Council, part of the Corbett HealthConnect communications company.

Toss Out Those Drugs

Several pharmacists have asked about proper disposal of controlled substances. The Office of Diversion Control within the Drug Enforcement Agency has published a list of return processors/reverse distributors who can assist in CDS elimination. The DEA cautions that the following list is not all-inclusive and urges pharmacists with questions to contact their local DEA office (Maryland's is the Division of Drug Control at (410) 764-2890).

| | |
|----------------------------------|----------------------|
| BFI Pharmaceutical Services | (404) 785-9710 |
| 3CI Complete Compliance | (800) 797-3837 |
| Reverse Distribution, Ltd. | (817) 868-5300 |
| Devos | (800) 483-2138 |
| Capitol Returns | (414) 527-9912 |
| EXP Pharmaceutical Waste | (510) 887-5750 |
| SAI Transport | (813) 858-7110 |
| Pharmaceutical Recovery Services | ... (407) 679-3400 |

Upcoming Health Events

Telephone numbers are provided for additional information and promotional materials.

February

American Heart Month (214) 373-6300

March

Cataract Awareness Month (708) 843-2020

Hemophilia Month (212) 819-8180

Mental Retardation Month (817) 261-6003

National Kidney Month (800) 622-9010

National Nutrition Month (800) 745-0775

Nutrition Awareness Month (404) 320-3333

Red Cross Month (202) 639-3185

Rosacea Awareness Month (708) 382-7404

Save Your Vision Week (5-11) (314) 991-4100

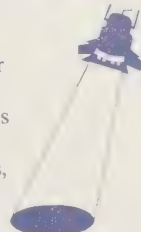
Poison Prevention Week (19-25) (301) 504-0580

Spotlight on Member Benefits

Are you taking full advantage of your membership in the Maryland Pharmacists Association?

Announced in November, the **AT&T Profit by Association** program provides for a group discount on long-distance telephone calls for small businesses. Regardless of whether you work in a traditional pharmacy, work as a full-time relief pharmacist, consultant pharmacist, or other pharmacy business, you'll want to call our MPhA AT&T program line at (800) 377-9942 for more details.

If Santa didn't bring you what you really wanted, you'll be delighted to hear about our newest benefit -- the **PharmArt Rebate Program**. PharmArt is a specialty catalog that carries nothing but pharmacy related materials -- glasses, ties, shirts, plaques, ornaments, mugs, nameplates, etc. For every purchase made by an MPhA member, PharmArt will contribute 10% of that purchase directly to the Association. For a copy of their catalog, call the MPhA offices at (800) 833-7587.



It's that time of the year when most of us renew our memberships in professional and trade organizations. And, if you're like most pharmacists, you're probably wondering whether to join yet one more association. To help reduce your dues and maximize your exposure to national organizations, MPhA is negotiating **First Year Dues Discounts** with the APhA, AMCP, ASCP and NARD. For example, MPhA members who join APhA for the first time would have their APhA dues reduced by 20%! If you've been considering joining one of our national groups, please call the MPhA offices *before* you do. We can help save you money.

Pharmacy Event Calendar

- February 9 MSHP Monthly Meeting, "Medical Malpractice," 6:00 pm, VA Medical Center. Call (410) 752-3318.
- February 16 MPhA Board of Trustees Meeting, MPhA Headquarters, 7:00 pm.**
- February 22 Eastern Shore CE Program, "New Drugs of 1994," Rustic Inn, Easton. 8:00-10:00 pm.
- February 26 CE Program, MPhA Mid-Year Meeting, Loews Hotel, Annapolis, Maryland. Call (800) 833-7587.**
- February 28 UMAB/Rx Alumni Association Meeting, 8:15 pm, Room 740, School of Pharmacy.
- March 9 "1995 Peter Lamy Memorial Lecture", 8:30 am, UMAB's Westminster Hall. Call (410) 706-5893.
- March 9 MPhA Board of Trustees Meeting, MPhA Headquarters, 7:00 pm.**
- March 9 MSHP Monthly Meeting, "Pain Control," 6:00 pm, St. Joseph's. Call (410) 752-3318.
- March 18-21 APhA Annual Convention, Orlando, Florida. Call APhA at (202) 628-4410.
- March 19 AZO Fritz Berman Memorial Seminar, "Prostate Cancer and Incontinence", Pikesville Holiday Inn
- March 19-25 National Poison Prevention Week. Call Lisa Booze at the Poison Center, (410) 706-7604 for details.
- March 22 Eastern Shore CE Program, "Anti-Anginal Therapy," Rustic Inn, Easton. 8:00-10:00 pm.
- March 26-28 NARD Legislative Conference, Washington, DC. Call NARD at (800) 544-7447.
- March 27-31 NARD Fitting School/Exam (OTC), Anaheim, CA. Call NARD at (800) 544-7447.
- March 28 UMAB/Rx Alumni Association Meeting, 8:15 pm, Room 740, School of Pharmacy.
- April 1 UMAB/Rx Open House for Prospective Pharmacy Students, (410) 7076-0756 to register.
- April 9 AZO CE Program, 9:30 am, Pikesville Holiday Inn. Call David Banks at (410) 465-5683.
- April 20 MPhA Board of Trustees Meeting, MPhA Headquarters, 7:00 pm.**
- April 24-29 NARD Fitting School/Exam (Camp), Milwaukee, WI. Call NARD at (800) 544-7447.
- April 25 UMAB/Rx Alumni Association Meeting, 8:15 pm, Room 740, School of Pharmacy.
- April 26 Eastern Shore CE Program, "Tuberculosis," Rustic Inn, Easton. 8:00-10:00 pm.
- May 8-12 NARD Fitting School/Exam (OTC), Dallas, TX. Call NARD at (800) 544-7447.
- May 18 MPhA Board of Trustees Meeting, MPhA Headquarters, 7:00 pm.**
- May 21 AZO CE Program, 9:30 am, Pikesville Holiday Inn. Call David Banks at (410) 465-5683
- June 18-21 MPhA Annual Convention, A New Frontier for Pharmacy, Ocean City**

NEWSLETTER

The Maryland Pharmacists Association

650 Lombard Street
Baltimore, Maryland 21201

MARYLAND PHARMACIST

February 1995

Vol. 71, No. 2

- Legislators
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- Pharmacist
with a Dream
- CE: New
Respiratory
Agents
- Numbers Game
- The MP Profile:
Rhea del Rosario
- Interactions with
the School
- Too Late
Lawsuit





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MARYLAND PHARMACIST

The Official Publication of The Maryland Pharmacists Association

February 1995

4 President's Commentary

MPhA President Arnold Davidov tells you why every pharmacist should care about the 1995 Maryland General Assembly.

5 The Substitution Dilemma

Generic substitution is something we all are familiar with.... or are we? This first in a two-part series on substitution issues looks at how to protect yourself and your patients.

10 Playing by the Numbers

A light-hearted look at all the different numbers the Board of Pharmacy expects you to remember and follow.

14 Interactions

Dean David Knapp talks about competence, education and advice.

15 The 1995 Legislative Directory

The 1994 elections brought a lot of new faces to the Maryland legislature. Here's a complete "clip and save" list for you to use in contacting and communicating your voice to elected leaders.

19 Maryland's Entrepreneurs

Marcus Carson knows you can't give up on a dream. This month's profile shows that determination, and a little luck, can make your dream of private practice come true.

22 Continuing Education

This month we present Part IV in our ongoing update of new drugs and drug therapies. Featured are respiratory products. Don't forget to complete the CE quiz on page 30 for credit! It's *free* for all MPhA members.

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The Maryland Pharmacist (ISSN 0025-4347) is published monthly by the Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201-1572. Annual subscription - \$10. Single issue copy, \$1.50. Members of the Maryland Pharmacists Association receive the publication as part of their annual membership dues. Entered as second class matter at Baltimore, Maryland and additional mailing offices.

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Postmaster: Send address changes to MPhA, 650 West Lombard Street, Baltimore MD 21201.

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Whenever the opportunity arises, please thank them for their support.

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President's Commentary

Politics.... Who Cares?

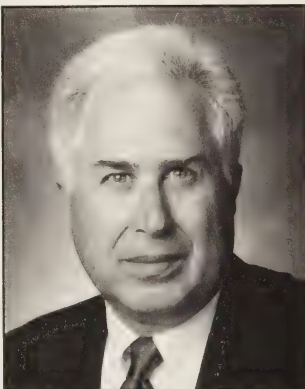
Well, the papers and the evening news are off and running again. You've seen the headlines.... "New Legislators Descend on Annapolis." You've heard the lead-ins from television announcers.... "Today, the Maryland General Assembly took up the controversial issue of".....

Blah, blah, blah. What could be more mind-numbing than the continuous media bombardment about politics, legislators, and the governmental process? To be perfectly honest, most of us would be just as happy to never hear another word about what's going on in either Washington or Annapolis. And, if we can't turn off the television, radio or avoid the papers, we'll just pretend that politics and government don't affect us at all.

That's the way I used to feel. For years, my pharmacy and my practice were just fine without government. Sure, I used to grumble about tax increases and the seemingly endless stream of red-tape that ties pharmacists up in following silly rules and senseless regulations. One day I discovered that some local physicians intended to open a drug dispensing cabinet in their offices -- supposedly to save their patients the trip to my local pharmacy. Losing long-term patients to doctor-dispensers was the catalyst that got me involved in the Association, and subsequently, into pharmacy politics.

You see, if I hadn't gotten mad (and gotten involved), I would never have helped implement one of the country's most comprehensive laws regulating prescriber dispensing of prescription drugs. If I hadn't have had a *reason* to protect my own livelihood, I would have just continued to pretend that politics and government didn't have any impact on me.

Once I did get angry and did get involved, I realized that almost everything that affects pharmacy can be equally affected through the legislative process. Third-parties treating you unfairly? Seek a legislative remedy. Tired of having to put a red "C" on controlled substances prescriptions? Go to the Board of Pharmacy and Division of Drug Control and get the regulation changed.



Arnold Davidov, P.D.

1994-1995 MPPhA President

MPPhA knows you don't have time to follow all the hundreds of potential pharmacy laws and regulations that are proposed each year. No individual pharmacist, busy serving their patients and managing their practice, has that kind of time. That's one of the services our members pay for.

MPPhA tracks, testifies, and lobbies for legislation that helps pharmacists and pharmacies. We do the same to "kill" legislation that hurts us.

But we can't do it alone. Surveys have shown that the most effective lobbyist isn't the high paid lawyer whispering in the ears of a legislator.

Instead, it's the individual voter, back in that legislator's community, whose one phone call or one letter can convince that legislator why he or she should support or oppose legislation or regulations. That's why your *personal* attention and involvement to legislative activities is so important. **You really can make a difference!** I know, I did it!

I don't know what issue will get you mad enough to contact a legislator. Maybe it's those dumb red "C" stamps. Maybe it's the threat of losing more patients to closed pharmacy networks. Maybe it's having your license fee raised, again.

Whatever your "hot button" is, I hope that when MPPhA asks for your help to fight for or against proposed legislation, we'll be able to help you to turn it on.

MP

The Substitution Dilemma

When What's Right and What's Real Aren't Always The Same Thing

David G. Miller, P.D., Executive Director
Maryland Pharmacists Association



Cast your mind back, back to those eighth grade civics classes. Remember some teacher

forcing you to learn the difference between "juris et de jure" and "de facto" governments?

No? Well, here's a quick reminder. A "juris et de jure" government is one that is legitimate, legal and consistent with a country's constitution. A "de facto" government is one that, although not legal and not legitimate, is the one that is in charge. For example, the recent turmoil in Haiti was because of the conflict between the "de jure" legally elected government of exiled President Jean Bertrande Aristide and the "de facto" military dictatorship of General Cedras.

So what does a civics class have to do with pharmacy? There is a direct relationship between the concepts of "de jure/de facto" and both generic and therapeutic substitution of pharmaceuticals.

Maryland was one of the pioneer states to adopt legislation permitting pharmacists to generically substitute. The law, section 508 of the Maryland Pharmacy Act, is quite clear and concise. A pharmacist may substitute a generically equivalent drug product, of the same dosage form and strength, for any brand name product prescribed, if: 1) the authorized prescriber doesn't expressly forbid substitution; 2) the substitution is recognized by in the *United States Food and Drug Administration's Current List of Approved Drug Products with Therapeutic Equivalence Evaluations*; and, 3) The consumer is charged less for the substituted drug than the price of the brand name drug.

Let's take a closer look at that second requirement. In 1980, the FDA first published the *United States Food and Drug Administration's Current List of Approved Drug Products with Therapeutic Equivalence Evaluations*. Now commonly called *The Orange Book* because its cover is orange, this publication lists all drug products approved by the FDA as safe and effective. In addition, it also lists those products for which pharmaceutical manufacturers have received approval for production of generic drugs whose patents have expired. *The Orange Book* does not list those drugs marketed prior to 1938 (phenobarbital, digoxin, levothyroxine) as these products predate the passage of the Food Drug and Cosmetic Act which required testing for the safety of products.

It also does not list those drugs marketed between 1938 and 1962 which were approved for safety but are still under review for effectiveness. The information in *The Orange Book* is also available in the USP/DI and the ABC book published by Facts and Comparisons.

Pharmacists using *The Orange Book* or its alternate sources to make substitution decisions have pointed out how confusing the FDA rating system is. In short, if a drug product is rated "A" the FDA considers it to be therapeutically equivalent to other pharmaceutically equivalent products. If a drug product is rated "B" the FDA has concluded that the product is not equivalent to other products. Table 1 gives a general explanation of each of the FDA's rating codes.

Maryland has an additional provision that permits a state-override of the FDA's generic substitution decisions. There are six specific drug products that are exempt from substitution in Maryland because of perceived problems with product equivalency. These products are: warfarin, phenytoin, valproic acid, primidone, theophylline sustained release, and carbamazepine. Maryland legislators also provided the Department of Health and Mental Hygiene with the ability to restrict substitution of other products if necessary.

For many years, the decision to dispense a generic substitute was one made with the input of the patient, the pharmacist and the prescriber. Now, the involvement of third-party payors

in the pharmacy marketplace has drastically changed that decision making process. A patient's right to a non-generic may be denied entirely by their prescription plan benefit design -- no generic means no coverage.

| Rating | Explanation |
|--------|--|
| AA | Products in conventional dosage forms without bioequivalence problems. |
| AN | Solutions and powders for aerosolization (bioequivalent). |
| AO | Injectable oil solutions (bioequivalent). |
| AP | Injectable aqueous solutions (bioequivalent). |
| AT | Topical products (bioequivalent). |
| AB | Products which had actual or potential bioequivalence problems and which are resolved by adequate testing (bioequivalent). |
| BC | Extended release dosage forms --tablets, capsules, injectables (not bioequivalent). |
| BD | Active ingredients and dosage forms with actual problems (not bioequivalent). |
| BE | Delayed release oral dosage forms (not bioequivalent). |
| BN | Solutions and powders for aerosolization (not bioequivalent). |
| BP | Active ingredients and dosage forms with potential problems (not bioequivalent). |
| BR | Suppositories or enemas for systemic use (not bioequivalent). |
| BS | Products which have drug standard deficiencies (not bioequivalent). |
| BT | Topical products (not bioequivalent). |
| BX | Products for which there is insufficient information to determine equivalence. |

Table I



Finding the Right Balance

The 1995 MPhA Mid-Year Educational Meeting

Sunday, February 26, 1995

Loews Annapolis Hotel, Annapolis, Maryland

Program

- 8:00 am Arrivals, Registration and Continental Breakfast
- 9:00 am *Continuing Education Seminar*
Your Duty to Warn:
Pharmacists Legal Liability
Gerald Mazzucca
SPONSORED BY BOOTS
- 10:30 am *Continuing Education Seminar*
New Drugs and Drug Therapies I
Robert Kerr, Pharm.D.
David Roffman, Pharm.D.
SPONSORED BY MERCK
- 12:30 noon Luncheon
- 1:30 pm *Professionwide Business Session*
Board of Pharmacy Nominee Presentations
SPONSORED BY SEARLE AND SMITHKLINE BEECHAM
- 2:30 pm *Continuing Education Seminar*
New Drugs and Drug Therapies II
- 4:00 pm *MPhA House of Delegates Session*

Registration

Early registration for this program is \$50 for MPhA members (\$60 for non-members) if received by MPhA by February 1, 1995. Thereafter, registration prices increase to \$60 for members (\$70 for non-members). To register for the 1995 MPhA Mid-Year Meeting, complete and detach the accompanying registration form. Return the form with payment (check or money order or credit card information) to the MPhA offices. For further information or questions, contact MPhA at (410) 727-0746 or (800) 833-7587.

This program will provide attendees with 5 hours of continuing education credits. The MPhA Mid-Year Meeting is made possible through the generous sponsorship of the following companies: Astra/Merck, Boots, Searle, SmithKline Beecham, Merck, Miles, Pfizer, Schering, Ortho Pharmaceuticals, Apothecon.

Learning Objectives

At the conclusion of this program, the attendee will be able to:

- Describe the impact of recent court decisions against pharmacists as it pertains to increase professional responsibility.
- List three strategies that pharmacists can take to reduce their risk of liability and increase pharmaceutical care to patients.
- Compare new drugs with previously available agents.

1995 MPhA Mid-Year Meeting

February 26, 1995

Loews Annapolis Hotel

\$50.00 MPhA Members/\$60.00 Non-Members *before February 1, 1995*

\$60.00 MPhA Members/\$70.00 Non-Members *after February 1, 1995*

☐ Charge my _____ VISA _____ MasterCard ☐ Check/Money Order Enclosed

Credit Card # _____ Expiration _____

Name _____

Address _____

City/State/ZIPcode _____

- ☐ Please consider me for appointment as an At-Large Delegate
Return Registration Form with payment to:

MPhA Mid-Year Registration

650 West Lombard Street, Baltimore, Maryland 21201-1572

Alternatively, the patient must pay the difference between what the program would reimburse for the generic and the cost of the branded product they want. The result of these policies? "De facto" mandatory generic substitution.

Third-party payors' zealous attempts to reduce costs by mandating generic substitution in all cases may not be in the best interests of the patients they cover. According to findings from a national pharmacy survey recently released at the American Association of Pharmaceutical Scientists meeting in San Diego,

that "the majority of retail pharmacists believe that managed care plans have forced them and their patients to use generics when, in the pharmacists' professional opinion, generics were not in the best interest of their patients." Banahan's findings also looked at the cost versus care impact of mandatory generic substitution. "Mandatory use of generics is not always cost-effective. Some retail pharmacists reported cases where up to three times as much of the generic drug was needed to maintain effective therapeutic levels."

Protection

So, what can you do to ensure that your patients are receiving appropriate generic products? What can you do to minimize any potential liability that may occur from providing a generic substitute?

First, any generic substitution must be made with the knowledge and/or authorization of the prescriber. In Maryland, a physician must indicate "Brand Medically Necessary",

"Brand Necessary," or "Dispense as Written" on the face of the prescription in order to prevent generic substitution (for Medicaid prescriptions, the "DAW" phrase is *not* acceptable). If these phrases do not appear, a pharmacist may legally substitute a recognized generic.

Second, generic substitution should be made with the knowledge and approval of the patient. While indicating the generic name and manufacturer on the label is generally considered to be sufficient notice, careful pharmacists should personally communicate to the patient that a substitution has been made. This gives the patient an opportunity to express any reservations about generic products and to share their concerns with you, their pharmacist.

Third, pharmacists must be familiar with which products are "AB" recognized generic substitutes *before* dispensing to the patient. For example, an "AB" rated methyldopa is considered by the federal and state laws to be generically equivalent to Aldomet. A conjugated estrogen product is not "AB" rated to Wyeth-Ayerst's Premarin and therefore not substitutable. Schering's albuterol inhalers (Proventil) are not generic substitutes for Glaxo's Ventolin. Vice-versa, a Ventolin inhaler is not a generic substitute for Proventil inhalers. They are not "AB" rated in the *Orange Book*. Levothyroxine products are not "AB" rated to Synthroid; nor is Synthroid "AB" rated to another company's levothyroxine. In these instances, the pharmacist must obtain the prescriber's approval for an entirely new prescription.

These last few examples represent the growing trend of "de facto" therapeutic substitution which will be covered in next month's issue of *The Maryland Pharmacist*.

MP



60 percent of community pharmacists feel pressure from managed care plans to dispense generic drugs, even when they believe it isn't in the best interest of their patients.

Benjamin Banahan, associate director of health services research at the University of Mississippi School of Pharmacy's Research Institute of Pharmaceutical Sciences reported



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Sunday, March 19, 1995

Holiday Inn, Pikesville
Reisterstown Road and the Beltway

Program

8:45 - 9:00 am
9:00 - 9:45 am
9:45 - 12:45 pm

Registration
Full Buffet Breakfast
Fritz Berman Seminar
Jeffery Chircus, M.D., Urologist
3 CEU's Awarded

To Register

Complete the registration form below and mail by March 12, 1995 with payment to: David Banks, 3813 Brentford Road, Randallstown, Maryland 21133.

- ☐ AZO Member or Spouse (\$10 in advance)
- ☐ Non-AZO Members (\$20 in advance)
- ☐ AZO Undergraduate Members (No charge)
- ☐ At Door Registration (\$30 members and non-members)

Name _____

Number in Party _____

Amount Enclosed _____

Playing by the Numbers

*Melvin Rubin, P.D., Secretary and Commissioner
Maryland State Board of Pharmacy*



umbers can
generate
great
excitement in
our lives

Did 181734 win the lottery?!!

Numbers can be of great interest
to many people...

*Has Ripken played in
2130 straight games yet?*

Numbers control our lives in
many ways...

*"You were going 85 in a
30 mile zone, Ma'am."*

Numbers can cause great
concern...

*How can I divide \$600 a
week into 2 alimony
payments, 4 child support
payments, and have
enough left over to buy a
Mercedes?*

Numbers are a big part of
your professional pharmacy life,
from indicating the proper
strength and quantity of a drug to
guiding you through a maze of
laws and regulations.

Results from Board of
Pharmacy law exams indicate that
there is confusion particularly
since there is no common
denominator in the numbers
required to comply with various
regulations.

For example, do you know
how many years you must keep
your continuing education credits
in case of an audit? How many
years must you retain prescription
records? How many years must
you retain your biennial inventory
of controlled substances?

CE credits must be kept for
four years and made available to
the Board if you are audited.

Records of original and
refilled prescriptions must be
retained for five years, up to
seven years for some third-
parties.

The biennial inventory of
controlled substances, the Form
222's and purchase documents
need only be kept until your next
inventory is done -- two years
down the road.

Here are some of the other
players in the numbers game:

A prescription must be
presented within 120 days of
writing by the prescriber to be
valid. Beyond that date you must
contact the prescriber for
authorization to fill it and note
on the prescription the date you
received the authorization.

A Medicaid prescription has a life of only 100 days once dispensed. This is a prime example of a third-party rule that is substantially different from the state law. Any refills for Medicaid, up to a maximum of two, have to be filled within that time frame. The original should have been filled within 10 days of writing or the same procedure must be followed as described in the above paragraph.

Controlled substances in Schedules III to V -- with appropriate prescriber authorization -- can be refilled five times within a limit of six months time from original date of the prescription.

The lesser of 34 days supply or 100 doses may be dispensed for amphetamines and methamphetamines. Note: that is 100 doses, not 100 tablets or 100 capsules. This allows you to give an almost unlimited amount depending on the dose. An extreme and unlikely example would be 3 tablets of Dexedrine 5mg TID. You almost need a calculator to come up to the maximum which can be dispensed (each day, 3 doses of 3 tablets are authorized times for each of 34 days equals 306 tablets). As an aside, note that this does not limit other Schedule II drugs even if the use overlaps, such as Ritalin.

Numbers, number, numbers -- perhaps a dream book would help.



Keep up with changes in your profession -- obtain at least 30 continuing education credits every two year renewal period. That's the law. By the way, be sure the course is taken during the renewal period you need it for and use it for that period. If you take a course in September and receive the certificate in October -- it's a September credit. If you are audited and the credits do not apply to the same year, it is likely that a new number will

be required by the Board -- some number higher than you would have had to obtain if you had watched the number of the month more carefully.

How many refrigerators must a pharmacist have to comply with the law (this is not an ethnic pharmacist joke). You need either one or two depending on whether you brown bag a lunch which must be refrigerated. One for medicine only according to law, and one for your tuna fish sandwich according to taste.

Licenses and permits..... You

need one as a pharmacist, one for your pharmacy, two to dispense CDS items (State and Federal), one if you distribute more than 5% of your sales to physicians, clinics, other pharmacies, etc., one if you manufacture, one if you distribute over 5% of your business. Then, you need a number of business licenses. This might all total into double figures.

Closing your pharmacy?

Sorry to hear that, but you must notify the Board at least 14 days prior to closing and again within 10 days after closing, with information required by regulation. Notify the Division of Drug Control at least 7 days in advance of closing for a closing inspection.

Forget to renew your license?

Really sorry to hear that. You can be reinstated, but the requirements depend on the numbers -- how many years has the license been expired? If less than two years you'll pay a late fee. If over two years -- even if you were practicing in another state -- you must still take the Maryland Law Examination all over again. Not practicing in another state? Sorry, but you have to take the Law Examination, practical, and reinstatement examination. If your license expired over five years ago and you haven't practiced in another state, expect to perform 1,000 hours of service in a community or hospital pharmacy and take the examinations listed above. It might be better just to renew on time. Make that your "Number One" priority.

How many items are listed in Title 12: Paragraph 313 (b), "Denials, reprimands, suspensions, and revocations"? The total as of

today is 26 general ways a pharmacist can get into trouble. It would be a good idea to read it sometimes. The number to use to obtain a copy of Maryland pharmacy laws from the Maryland Pharmacists Association is (410) 727-0746. To save a number of nickels use the toll-free number (800) 833-7587. The number you will have to pay is \$ 29.95 plus tax if you're a member and \$49.95 if not.

Questions regarding laws can be answered by a call to the Board of Pharmacy at either our local number, (410) 764-4755, or our 800 number, (800) 542-4964.

Number, numbers, numbers -- but no rules telling you the number of the winning horse.

Don't forget all the numbers on the prescription label -- number of the prescription, numbers in the dates, numbers in maximum expiration date, number of pills to take a number of times a day, number of refills.

Of course, if it is a third-party prescription you need a lot of other numbers in the computer before a number will come on a check to you.

MP



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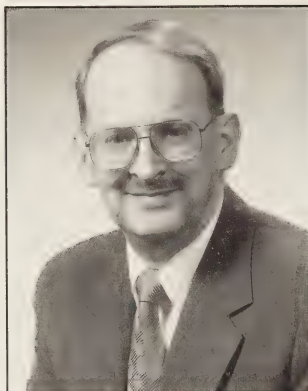
Competence, Education, and Advice

Competence is critical to a pharmacist. When a pharmacist meets one on one with a prescriber or patient, and the issue is critical drug therapy, you've got to be prepared to come up with a correct answer. The patient's health and your credibility depend on it. Pharmacists depend upon their schools of pharmacy to provide the quality of education necessary to produce competence. Quality education involves many things, not the least of which are a solid curriculum and excellence in teaching.

Our faculty at Maryland has benefited through the years from strong support and advice from the practice community on our educational endeavors. During our transition to the entry-level Doctor of Pharmacy program, this advice was channeled through an effective Transition Advisory Committee chaired first by Nick Lykos and then by Jerry Fine and consisting of a cross section of excellent pharmacists from across the state.

Now that the transition to the entry-level Pharm.D. degree is well under way and two classes have been admitted, an Educational Advisory Committee has been working for the last year to provide advice and counsel to the dean and faculty. Chaired by David Arrington and including the pharmacists listed below, the committee meets every other month to consider critical matters of teaching and educational policy. Each committee member serves a prescribed term and is charged with representing the best interests of the profession of pharmacy, not a particular organization, company or type of practice.

During its first year, topics considered included teaching communication skills, recruiting students with good communication aptitude, teaching problem solving throughout the curriculum, and dealing with employer/school concerns over student working arrangements.



David A. Knapp, Dean
UMAB School of Pharmacy

The committee is working well; but, even the best can work better. If you have identified concerns that should be considered, please talk with David Arrington, or me, or any member of the committee listed below. If you'd like to participate as a future member of the committee, give me a call at (410) 706-7651. Pharmaceutical education is the business of every pharmacist. It is the key to competence and to the future of the profession.

Members of the Educational Advisory Committee include: David Arrington, Chairman, Johns Hopkins Hospital; Stanton Ades, NeighborCare Pharmacies; Arnold Blaustein, Associated Prescription Services; Karim Calis, National Institutes of Health; Paul Cuzmanes, Wilson, Elser, Edelman & Dicke; Wayne Dyke, Rite Aid; Joseph DeMino, CVS; Murhl Flowers, Safeway; Ramona McCarthy-Hawkins, Food & Drug Administration; Robert Kabik, Giant Food Stores; Mark Levi, Medical Arts Pharmacy; Irving Lottier, Harlem Park Pharmacy; Robert Martin, Potomac Valley Pharmacy; Alicia Martinez, Giant Food Stores; David Miller, MPhA; Penney Miller, Searle; Joseph Ober, Advance-Paradigm; Richard Reitz, Columbia Medical Plan; Richard Rumrill, Howard County General Hospital; David Russo, Medicine Shoppe; Ernest Testerman, Elkton Pharmacy; Beverly Yachmetz, Health Connections. **MP**

The 1995 Maryland General Assembly

A Legislative Directory for Maryland Pharmacists

*Ernest Testerman, P.D., Phillip Marsiglia, P.D.
MPhA Health Care Policy Committee*



n Election Day, 1994, voters completely changed the face of the Maryland

General Assembly. Almost a third of the legislators sworn in on January 11, 1995 are new to Annapolis. Because there are so many new faces in Annapolis, we thought you could use this handy reference to all the new Delegates and Senators with their names, office locations, and telephone numbers.

Using the Directory

From time to time, MPhA may contact you through our state-wide FAX Alert Network for help in informing legislators where pharmacy stands on different issues. We may need you to call or write your Senator or Delegate about legislation (called "bills") that affect professional or economic issues important to pharmacy. Or, maybe there's a pressing issue involving your family or community for which you need a legislator's help.

Contacting a legislator is simple. All you need is this directory and your legislative district! If you don't know your legislative district, we've taken care of that for you. Just look at your mailing label on the front of this issue of *The Maryland Pharmacist*. Your district number, determined by our staff and former MPhA student trustee Rhea delRosario, from your mailing address, appears after the "LD" above your name.

Once you know where you are, just look up your district for the names of the Delegates and Senator elected in your area. If you're calling from the Baltimore area, use the "841" phone number appearing below the legislator's name. If you're calling from the Washington area, use the "858" phone number. (If you're not located in either area, try both of the numbers to see which one goes through.) In either case, it's a toll-free call. These phone numbers will connect you directly with the legislator's office.

If you prefer to write, address your communication to:

For Delegates

The Honorable [Name]
Lowe House Office Building
Annapolis, Maryland 21401-1991

For Senators

The Honorable [Name]
James Senate Office Building
Annapolis, Maryland 21401-1991.

The Delegate or Senator's room number appears below their name and following the appropriate office building.

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Delegate Betty Workman (D)
Lowe 320 841-3462 858-3462
Delegate Casper Taylor (D)
Lowe 209 841-3205 858-3205
Senator John Hafer (R)
James 100 841-3603 858-3603

District 2

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Lowe 321 841-3447 858-3447
Delegate D. Bruce Poole (D)
Lowe 321 841-3451 858-3451
Delegate John Donoghue (D)
Lowe 321 841-3447 858-3447
Senator Donald Munson (R)
James 405 841-3609 858-3609

District 3

Delegate Sue Hecht (D)
Lowe 324 841-3240 858-3240
Delegate Louise Snodgrass (R)
Lowe 324 841-3240 858-3240
Delegate J. Anita Stup (R)
Lowe 324 841-3240 858-3240
Senator John Derr (R)
James 408 841-3575 858-3575

District 4

Delegate David Brinkley (R)
Lowe 323 841-3107 858-3107
Delegate Paul Stull (R)
Lowe 323 841-3107 858-3107
Delegate Donald Elliott (R)
Lowe 323 841-3107 858-3107
Senator Timothy Ferguson (R)
James 403 841-3704 858-3704

District 5

Delegate Richard Dixon (D)
Lowe 322 841-3371 858-3371
Delegate Joseph Getty (R)
Lowe 322 841-3371 858-3371
Delegate Nancy Stocksdaile (R)
Lowe 322 841-3371 858-3371
Senator Larry Haines (R)
James 401 841-3683 858-3683

District 6

Delegate Diane DeCarlo (D)
Lowe 303 841-3384 858-3384
Delegate Kenneth Holt (R)
Lowe 303 841-3384 858-3384
Delegate Michael Weir (D)
Lowe 303 841-3384 858-3384
Senator Michael Collins (D)
James 216 841-3642 858-3642

District 7

Delegate John Arnick (D)
Lowe 426 841-3458 858-3458
Delegate Joseph Minnick (D)
Lowe 305 841-3332 858-3332
Delegate Jacob Mohorovic (D)
Lowe 305 841-3334 858-3334
Senator Norman Stone, Jr. (D)
James 841-3587 858-3587

District 8

Delegate Katherine Klausmeier (D)
Lowe 307 841-3365 858-3365
Delegate James Ports (R)
Lowe 307 841-3365 858-3365
Delegate Alfred Redmer, Jr. (R)
Lowe 307 841-3365 858-3365
Senator Thomas Bromwell (D)
James Wing 841-3620 858-3620

District 9

Delegate Wade Kach (R)
Lowe 308 841-3359 858-3359
Delegate Martha Klima (R)
Lowe 308 841-3359 858-3359
Delegate James Kelly (R)
Lowe 308 841-3359 858-3359
Senator F. Vernon Boozer (R)
James 410 841-3706 858-3706

District 10

Delegate Emmett Burns, Jr. (D)
Lowe 309 841-3350 858-3350
Delegate Shirley Nathan-Pullman (D)
Lowe 309 841-3350 858-3350
Delegate Joan Parker (D)
Lowe 309 841-3350 858-3350
Senator Delores Kelley (D)
James 209 841-3606 858-3606

District 11

Delegate Michael Finifter (D)
Lowe 306 841-3342 858-3342
Delegate Robert Frank (D)
Lowe 306 841-3342 858-3342
Delegate Dan Morhaim (D)
Lowe 306 841-3342 858-3342
Senator Paula Hollinger (D)
James 206 841-3131 858-3131

District 12

Delegate Elizabeth Bobo (D)
Lowe 209 841-3205 858-3205
Delegate James Malone, Jr. (D)
Lowe 304 841-3378 858-3378
Delegate Donald Murphy (R)
Lowe 304 841-3378 858-3378
Senator Edward Kasemeyer (D)
James 309 841-3653 858-3653

District 13

Delegate John Morgan (R)
Lowe 226 841-3200 858-3200
Delegate Shane Pendergrass (D)
Lowe 209 841-3205 858-3205
Delegate Frank Turner (D)
Lowe 209 841-3205 858-3205
Senator Martin Madden (R)
James 402 841-3572 858-3572

District 14

Delegate Patricia Faulkner (R)
Lowe 219 841-3052 858-3052
Delegate Robert Flanagan (R)
Lowe 226 841-3200 858-3200
Delegate Robert Kittleman (R)
Lowe 411 841-3041 858-3041
Senator Christopher McCabe (R)
James 404 841-3671 858-3671

District 15

Delegate Jean Cryor (R)
Lowe 219 841-3052 858-3052
Delegate Richard LaVay (R)
Lowe 405 841-3090 858-3090
Delegate Mark Shriver (D)
Lowe 224 841-3046 858-3046
Senator Jean Roesser (R)
James 308 841-3169 858-3169

District 16

Delegate Gilbert Genn (D)
Lowe 220 841-3045 858-3045
Delegate Marilyn Goldwater (D)
Lowe 221 841-3019 858-3019
Delegate Nancy Kopp (D)
Lowe 221 841-3019 858-3019
Senator Brian Frosh (D)
James 202 841-3124 858-3124

District 17

Delegate Kumar Barve (D)
Lowe 222 841-3001 858-3001
Delegate Michael Gordon (D)
Lowe 151 841-3519 858-3519
Delegate Cheryl Kagan (D)
Lowe 224 841-3046 858-3046
Senator Jennie Forehand (D)
James 214 841-3134 858-3134

District 18

Delegate Leon Billings (D)
Lowe 223 841-3028 858-3028
Delegate Sharon Grosfeld (D)
Lowe 223 841-3028 858-3028
Delegate John Hurson (D)
Lowe 313 841-3464 858-3464
Senator Christopher VanHollen (D)
James 304 841-3137 858-3137

District 19

Delegate Henry Heller (D)
 Lowe 429 841-3528 858-3528
 Delegate Adrienne Mandel (D)
 Lowe 220 841-3045 858-3045
 Delegate Carol Petzold (D)
 Lowe 222 841-3001 858-3001
 Senator Leonard Teitelbaum (D)
 James 205 841-3151 858-3151

District 20

Delegate Dana Dembrow (D)
 Lowe 219 841-3052 858-3052
 Delegate Peter Franchot (D)
 Lowe 424 841-3460 858-3460
 Delegate Sheila Hixson (D)
 Lowe 100 841-3469 858-3469
 Senator Ida Ruben (D)
 James 204 841-3634 858-3634

District 21

Delegate Barbara Frush (D)
 Lowe 210 841-3114 858-3114
 Delegate Pauline Menes (D)
 Lowe 210 841-3114 858-3114
 Delegate James Rosapepe (D)
 Lowe 100 841-3521 858-3521
 Senator Arthur Dorman (D)
 James 116 841-3141 858-3141

District 22

Delegate Rushern Baker, III (D)
 Lowe 207 841-3058 858-3058
 Delegate Anne Healey (D)
 Lowe 207 841-3058 858-3058
 Delegate Richard Palumbo (D)
 Lowe 207 841-3058 858-3058
 Senator Paul Pinsky (D)
 James 303 841-3155 858-3155

District 23

Delegate Mary Conroy (D)
 Lowe 208 841-2098 858-2098
 Delegate James Hubbard (D)
 Lowe 208 841-3103 858-3103
 Delegate Joan Pitkin (D)
 Lowe 208 841-3098 858-3098
 Senator Leo Green (D)
 James 212 841-3631 858-3631

District 24

Delegate Joanne Benson (D)
 Lowe 204 841-3065 858-3065
 Delegate Nathaniel Exum (D)
 Lowe 201 841-3074 858-3074
 Delegate Carolyn Howard (D)
 Lowe 204 841-3065 858-3065
 Senator Decatur Trotter (D)
 James 313 841-3148 858-3148

District 25

Delegate Michael Crumlin (D)
 Lowe 203 841-3076 858-3076
 Delegate Dereck Davis (D)
 Lowe 203 841-3076 858-3076
 Delegate Brenda Hughes (D)
 Lowe 203 841-3076 858-3076
 Senator Ulysses Currie (D)
 James 100 841-3127 858-3127

District 26

Delegate C. Anthony Muse (D)
 Lowe 205 841-3012 858-3012
 Delegate Obie Patterson (D)
 Lowe 205 841-3012 858-3012
 Delegate David Valderrama (D)
 Lowe 205 841-3012 858-3012
 Senator Gloria Lawlah (D)
 James 314 841-3092 858-3092

District 27

Delegate George Owings, III (D)
 Lowe 217 841-3231 858-3231
 Delegate James Proctor, Jr. (D)
 Lowe 206 841-3083 858-3083
 Delegate Joseph Vallario, Jr. (D)
 Lowe 121 841-3488 858-3488
 Senator Thomas "Mike" Miller (D)
 State House 841-3700 858-3700

District 28

Delegate Thomas Hutchins (R)
 Lowe 216 841-3247 858-3247
 Delegate Samuel Linton (D)
 Lowe 216 841-3247 858-3247
 Delegate Van Mitchell (D)
 Lowe 216 841-3247 858-3247
 Senator Thomas Middleton (D)
 James 210 841-3616 858-3616

District 29

Delegate Anthony O'Donnell (R)
 Lowe 217 841-3314 858-3314
 Delegate John Slade, III (D)
 Lowe 217 841-3314 858-3314
 Delegate John Wood, Jr. (D)
 Lowe 141 841-3502 858-3502
 Senator Roy Dyson (D)
 James 215 841-3673 858-3673

District 30

Delegate Phillip Bissett (R)
 Lowe 212 841-3211 858-3211
 Delegate Michael Busch (D)
 Lowe 151 841-3519 858-3519
 Delegate Virginia Clagett (D)
 Lowe 212 841-3211 858-3211
 Senator John Astle (D)
 James Wing 841-3578 858-3578

District 31

Delegate Joan Cadden (D)
 Lowe 213 841-3217 858-3217
 Delegate John Leopold (R)
 Lowe 213 841-3217 858-3217
 Delegate Victoria Schade (R)
 Lowe 213 841-3217 858-3217
 Senator Philip Jimeno (D)
 James 316 841-3658 858-3658

District 32

Delegate Michael Burns (R)
 Lowe 215 841-3223 858-3223
 Delegate Mary Ann Love (D)
 Lowe 215 841-3233 858-3233
 Delegate James Rzepkowski (R)
 Lowe 215 841-3233 858-3233
 Senator Edward Middlebrooks (R)
 James 302 841-3593 858-3593

District 33

Delegate Robert Baldwin (R)
 Lowe 214 841-3223 858-3223
 Delegate Janet Greenip (R)
 Lowe 214 841-3223 858-3223
 Delegate Marsha Perry (D)
 Lowe 214 841-3223 858-3223
 Senator John Cade (R)
 James 407 841-3568 858-3568

District 34

Delegate Rose Mary Bonsack (D)
 Lowe 326 841-3289 858-3289
 Delegate Nancy Jacobs (R)
 Lowe 326 841-3289 858-3289
 Delegate Mary Louise Preis (D)
 Lowe 326 841-3289 858-3289
 Senator David Craig (R)
 James 307 841-3158 858-3158

District 35

Delegate Donald Fry (D)
 Lowe 326 841-3289 858-3289
 Delegate James Harkins (R)
 Lowe 326 841-3289 858-3289
 Delegate David Rudolph (D)
 Lowe 403 841-3444 858-3444
 Senator William Amoss (D)
 James 100 841-3603 858-3603

District 36

Delegate Wheeler Baker (D)
 Lowe 422 841-3189 858-3189
 Delegate Ronald Guns (D)
 Lowe 161 841-3534 858-3534
 Delegate Peter Hammen (D)
 Lowe 316 841-3303 858-3303
 Delegate Mary Walkup (R)
 Lowe 423 841-3449 858-3449

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James 301 841-3639 858-3639

District 37

Delegate Adelaide Eckardt (R)
Lowe 404 841-3343 858-3343
Delegate Don Hughes (D)
Lowe 414 841-3427 858-3427
Delegate Kenneth Schisler (R)
Lowe 415 841-3429 858-3429
Senator Richard Colburn (R)
James 311 841-3590 858-3590

District 38

Delegate Bennett Bozman (D)
Lowe 413 841-3431 858-3431
Delegate Norman Conway (D)
Lowe 416 841-3425 858-3425
Delegate Norman McClenahan (R)
Lowe 412 841-3433 858-3433
Senator J. Lowell Stoltzfus (R)
James 409 841-3645 858-3645

District 39

Delegate Raymond Beck (R)
Lowe 225 841-3037 858-3037
Delegate Barrie Ciliberti (R)
Lowe 225 841-3037 858-3037
Delegate Mathew Mossburg (R)
Lowe 225 841-3037 858-3037
Senator Patrick Hogan (R)
James 368 841-3686 858-3686

District 40

Delegate Tony Fulton (D)
Lowe 317 841-3277 858-3277
Delegate Salima Marriott (D)
Lowe 317 841-3277 858-3277
Delegate Howard Rawlings (D)
Lowe 131 841-3407 858-3407
Senator Ralph Hughes (D)
James 310 841-3656 858-3656

District 41

Delegate Frank Boston, Jr. (D)
Lowe 314 841-3283 858-3283
Delegate Margaret Murphy (D)
Lowe 314 841-3283 858-3283
Delegate Nathaniel Oaks (D)
Lowe 314 841-3283 858-3283
Senator Clarence Blount (D)
James 201 841-3697 858-3697

District 42

Delegate James Campbell (D)
Lowe 319 841-3297 858-3297
Delegate Maggie McIntosh (D)
Lowe 319 841-3297 858-3297
Delegate Sandy Rosenberg (D)
Lowe 319 841-3297 858-3297
Senator Barbara Hoffman (D)
James 100 841-3648 858-3648

District 43

Delegate Gerald Curran (D)
Lowe 141 841-3502 858-3502
Delegate Ann Marie Doory (D)
Lowe 121 841-3476 858-3476
Delegate Kenneth Montague (D)
Lowe 310 841-3259 858-3259
Senator John Pica (D)
James 402 841-3145 858-3145

District 44

Delegate Elijah Cummings (D)
Lowe 312 841-3391 858-3391
Delegate Ruth Kirk (D)
Lowe 315 841-3263 858-3263
Delegate Clarence Mitchell, IV (D)
Lowe 315 841-3263 858-3263
Senator Larry Young (D)
James 306 841-3612 858-3612

District 45

Delegate Talmadge Branch (D)
Lowe 301 841-3257 858-3257
Delegate Clarence Davis (D)
Lowe 301 841-3257 858-3257
Delegate Hattie Harrison (D)
Lowe 427 841-3486 858-3486
Senator Nathaniel McFadden (D)
James 208 841-3165 858-3165

District 46

Delegate Cornell Dypski (D)
Lowe 316 841-3303 858-3303
Delegate Carolyn Krysiak (D)
Lowe 316 841-3303 858-3303
Senator Perry Sfikas (D)
James 211 841-3598 858-3598

District 47

Delegate Thomas Dewberry (D)
Lowe 304 841-3378 858-3378
Delegate Brian McHale (D)
Lowe 310 841-3319 858-3319
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Maryland Pharmacists

The Entrepreneurs

This Month

*Marcus Carson, Pharmacist
Randallstown Medical Center Pharmacy
Randallstown, Maryland*



Marcus Carson had the undivided attention of his preceptor students as he spoke. They listened intently while he described his dream of one day owning his own pharmacy.

Marcus told the students about the importance of having a neighborhood source of prescriptions. He explained why a pharmacy should have good "front end" sales, with a variety of merchandise. As the students from Howard University and the University of Maryland listened, they couldn't help daydreaming about the possibility of one day owning their own pharmacies. Never mind that Dr. Carson was not yet an owner. He was managing a busy independent pharmacy in a professional building.

Everyone knew one day Marcus Carson would indeed own his own store. The question was not *if* Marcus would have a pharmacy of his own, it was *when*.

For him, the answer came in 1980. He learned that Macy Meyers was selling a pharmacy in Randallstown. He and his family had recently moved to Randallstown from Washington, DC. This store was only five minutes from his home and was located in the Randallstown Professional Center. Anyone else looking around the pharmacy would have seen a store that had light foot traffic and an unimaginative and outdated mix of merchandise.

When Marcus looked, *he* saw potential.

After he purchased the pharmacy, Marcus began to slowly implement the changes he felt were necessary to modernize and capture new business. He was careful not to make the changes too quickly since so many of the loyal patients were used to the "old" Randallstown Pharmacy and he didn't want to drive them away.

One of the first changes to take place was out of the sight of his customers. Since his pharmacy is located only a few blocks from the Northwest Hospital Center, Marcus became an active member of the Hospital Fund Raising Committee (he now sits on the Board of this Committee). This not only helped the hospital his own family uses but also lead to important business contacts. He expanded the durable medical equipment lines carried by his pharmacy and added an ostomy supply section. He began delivery service all over northwest Baltimore County and later expanded this service to include the entire city as well.

In 1983, Marcus obtained a liquor license and began selling beer, wine, and spirits. He separated this section from the rest of the store in such a way that he could oversee its operations from his prescription counter but wouldn't be intrusive to those seeking only pharmacy services. To further increase foot traffic, he added daily Lottery and scratch-off games, a low cost photocopy center, and a discount film developing department. He removed an outdated cosmetic center and replaced it with a full service video department with \$1.00 rentals, incentives for frequent renters and began to sell used movies when the demand for a particular title diminished.

Recognizing the need for an independent owner to maximize buying potential, Marcus joined the Maryland Professional Pharmacies/EPIC buying group at its inception. Today, he sits on its Executive Board. He is a member of MPhA, NARD and APHA. His wife Regina is also a pharmacist and is on the faculty of the Howard University School of Pharmacy from which he graduated in 1970. Marcus is a family man with three sons and one daughter. He finds time to sing in his church choir and still has the first three dollars he made in his store proudly displayed behind the pharmacy counter.



In 1992, Marcus and fellow pharmacist Wesley Shelton formed a partnership called Hilton Court Pharmacies. In addition to the Randallstown Medical Center Pharmacy, there are three other pharmacies in the group (Garwyn Medical Center Pharmacy, Madison Park Pharmacy and Harlem Park Pharmacy).

In a way, this partnership has brought Marcus Carson's career full circle. It was at Garwyn Medical Center Pharmacy, which he managed from 1974 to 1980, that he first shared his dream of ownership with his students. He never imagined that his dream would one day once again bring his to Garwyn.

This time, however, *he* was one of the owners!

MP

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Litigation Update

Plaintiff Waits Too Long

A New York Appellate court recently upheld the dismissal of a claim brought against a pharmacy and a manufacturer, in which a patient had contended that the defendants had either dispensed or manufactured a harmful medication. The plaintiff was not diligent in pursuing her claim, and as a result the lawsuit was dismissed.

According to the court, the patient alleged that in November of 1982 she purchased an antibiotic manufactured by the defendant manufacturer at a pharmacy owned by the defendant pharmacy corporation. After opening the bottle and noticing a foul odor, the plaintiff alleged that she telephoned the pharmacist who told her that she could take the medication despite the foul odor. As a result of such ingestion, the plaintiff alleged that she experienced nausea, vomiting of blood, upper abdominal pain, and epigastric burning.

In June of 1984, the patient initiated a legal action alleging that the pharmacy had dispensed contaminated medication or that the manufacturer had negligently manufactured the medication. A long period followed during which discovery of records and other evidence was supposed to have occurred. In 1990, the plaintiff filed a notice with the court indicating that discovery was completed. At a conference held on May 3, 1991, the trial judge ordered the case to proceed to trial on June 11, 1991.



David B. Brushwood

On that day, however, the plaintiff appeared with a new attorney who advised the court that he could not proceed with the case even after the court offered a three week continuance. Over the strenuous objection of the defense counsel, the court rules that the matter could be restored to the trial calendar at a later time, but that no further discovery would be permitted.

On June 10, 1992, one day before the clerk of the court would have entered an automatic dismissal, the plaintiff appeared with yet another attorney, moved to restore the case, and requested additional time for discovery. The court denied the motion to restore, and dismissed the case for failure to establish a meritorious cause of action.

This ruling was affirmed on appeal, based on the rationale that none of the evidence available to the plaintiff contained sufficient specifics to establish a meritorious case. The law requires that those who initiate legal actions against others pursue them diligently. That requirement was not met in this case.

MP

Based on: *Maida v. Rite Aid Corporation*, 1994 Westlaw 671396 (NYAD December 1, 1994).

Continuing Education

This lesson reviews the new respiratory drugs: the non-sedating antihistamine loratidine (Claritin), the bronchodilator salmeterol (Serevent) and the antiasthmatic drug nedocromil (Tilade). Dosage forms and regimens are listed in Table 1.

The "1P" noted after the name of the drug signifies that it was given priority approval by FDA because the drug represented a significant advantage over previously available therapy. The "1S" notation means the drug went through the standard approval process.

New Antihistamine

Loratidine

Trade Name: Claritin (1S)

Loratidine is a derivative of azatidine (Optimine). It is a prodrug, meaning it is not active itself, but on absorption, it is converted in the liver into its active metabolite. It has a relatively rapid onset of action and a long duration. Most patients who obtain relief of hay fever symptoms reportedly do so within 2 hours, some within 30 minutes of administration.

Loratidine joins terfenadine (Seldane) and astemizole (Hismanal) in the nonsedating antihistamine (second-generation) category. They are indicated for allergic conditions. The most prevalent of those is allergic rhinitis, which reportedly affects 22 million Americans. Symptoms of allergic rhinitis include itching, increased secretion of fluid from the nasal mucosa, sneezing,

watery eyes, irritability and fatigue. The basic pharmacologic action of antihistamines, including loratidine, is the blockade of peripheral histamine receptors. This prevents histamine, a mediator of inflammation, from causing the symptoms of allergic rhinitis.

An advantage of the nonsedating antihistamines over the first-generation products is that they do not readily cross the blood-brain barrier. In the brain, histamine is a stimulatory neurotransmitter, so blocking its action there leads to sedation. Because loratidine does not block central nervous system histamine receptors, it does not cause significant drowsiness.

Loratidine was originally recommended for approval by FDA's Pulmonary-Allergy Drugs Advisory Panel in October 1987. Its manufacturer had planned to market it in 1988. Marketing was

delayed to resolve bioequivalence issues since most of the clinical trials were performed using a capsule dosage form.

However, the decision was made to market it as a tablet (presumably due to the Tylenol capsule/cyanide incident). FDA required the manufacturer to replicate its data using the tablets because they are not considered to be automatically bioequivalent to capsules. The delay took six years.

This was a good news/bad news scenario. The bad news for the manufacturer was that it realized no revenue from Claritin during that time period. The good news was that, because of legislation promulgated in 1985, the drug's patent was extended to 1998.

New Drug Review: Respiratory Agents

J. Richard Wuest, R. Ph., Pharm.D.

Professor of Pharmacy Practice, University of Cincinnati

Thomas A. Gossel, R. Ph., Ph.D., Interim Dean
Ohio Northern University

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New Respiratory Agents

| Generic Name | Trade Name | Availability | Dosage Regimen |
|--------------|------------|--|--|
| Loratidine | Claritin | 10 mg tablets | 10 mg daily |
| Nedocromil | Tilade | 16.2 mg canisters 112 actuations | 2 inhalations QID downward to BID |
| Salmeterol | Serevent | 6.5 g canisters 60 actuations 13 g canisters 120 actuations | 2 inhalations Q 12 hours morning and night |

Table 1

Also, by the time loratidine was released, its major competition - Seldane and Hismanal - had been implicated in a potentially serious side effect and drug interaction. Reports of cases of torsade de pointes (a cardiac arrhythmia characterized by prolonged QTc on EKG readings) associated with elevated plasma levels of Seldane and Hismanal had been published. Problems with concomitant use of erythromycin and ketoconazole occurred with overdoses as well as doses as low as twice the recommended daily dosage.

Because torsade de pointes is a life-threatening cardiac arrhythmia, the manufacturers of terfenadine and astemizole added a boxed warning to the package insert of their products. The warning contraindicates the use of these drugs in patients with significant hepatic dysfunction and warns against exceeding the recommended dose of 60 mg twice a day for terfenadine and 10 mg once daily for astemizole.

The macrolide antibiotics (specifically erythromycin and troleandomycin) and azole antifungals (specifically ketoconazole and itraconazole) interfere with the metabolism of terfenadine and astemizole resulting in higher blood levels of these two drugs. There is evidence that concurrent use increases the occurrence of cardiac arrhythmias and this has been added to the boxed warning contraindications.

While these drugs also inhibit the metabolism of loratidine, this has not caused a confirmed case of drug-induced QTc interval prolongation or torsade de pointes. In fact, a clinical evaluation of the co-administration of loratidine and ketoconazole was undertaken to study the outcome. It showed that even though ketoconazole raised serum levels of loratidine nearly twice normal values, and increased serum levels of its active metabolite over 50 percent, there were no related changes in the QTc intervals during the following 24 hours. There was no increase in any other adverse effect in the combination as compared to loratidine alone. Similar results were gathered from the study of loratidine and erythromycin. Therefore, loratidine may be a safer alternative for patients needing both a nonsedating antihistamine and either a macrolide antibiotic or azole antifungal.

Side effects reported for loratidine at the 3 percent or higher level are: headache (12 vs. 11 percent for the placebo), somnolence (8 vs. 9 percent), fatigue (4 vs. 3 percent) and dry mouth (3 vs. 2 percent).

Food has been reported to delay the time for Claritin to reach peak levels in the blood and to increase the total amount absorbed and metabolized. Its manufacturer recommends that the dosage be taken on a empty stomach. Additional information that can be used in counseling patients taking Claritin is listed in Table 2.

New Antiasthmatic

Salmeterol

Trade Name: Serevent (IP)

Salmeterol is an analog of albuterol, but because its structure binds firmly to the beta-2 adrenergic receptor protein, it remains anchored and comes in contact with the active portion of the receptor repeatedly. This extends its duration of action significantly. A single inhaled dose of salmeterol induces bronchodilation that lasts approximately twelve hours.

Salmeterol is about 10 times more potent than albuterol. It has much greater selectivity for the beta-2 receptors (which predominate in pulmonary tissue) than the beta-1 type (which predominate in the myocardial tissue). This is an ideal attribute for a bronchodilator because it allows therapeutic activity without cardiac side effects. It has been reported that if isoproterenol is used as the standard of equal affinity to both beta-1 and beta-2 receptors, albuterol is about 650 times more beta-2 specific. Salmeterol is approximately 50,000 times more beta-2 selective.

Asthma's Impact

Asthma is one of several chronic obstructive pulmonary disorders that is increasing in occurrence in the U.S. It has been estimated that asthma has increased nearly 40 percent in the last 10 years. Over 10 million Americans are now afflicted at a tremendous cost both financially and in quality of life. Health care expenditures for asthmatic patients represent approximately 1 percent of total health care costs in the U.S.

Asthma is difficult to define precisely as a disease state. An expert panel for the National Asthma Education Program has defined it as: "...a lung disease with the following characteristics:

- airway obstruction that is reversible (but not completely so in some patients) either spontaneously or with treatment;
- airway inflammation; and,
- increased airway responsiveness to a variety of stimuli."

The disease can also be described by its classic symptoms: wheezing, shortness of breath, chest tightness and cough. Patients with active asthma often awaken at night with one or more of these symptoms. They frequently have acute attacks on exposure to a number of stimuli including airborne pollutants and exercise. It is so common for these patients to suffer from attacks during the night that nocturnal asthma is considered to be its definitive diagnostic sign.

Inhaled beta-2 adrenergic agonists induce relaxation of bronchial smooth muscle to relieve the symptoms of asthma. They bind with beta-2 adrenergic receptors and set off a series of reactions which stimulate intracellular adenylyl cyclase, the enzyme that catalyzes conversion of adenosine triphosphate into cyclic adenosine monophosphate (cAMP).

Increased cAMP causes relaxation of bronchial smooth muscle and inhibits release of mediators of hypersensitivity (allergy) from mast cells and other cells involved in the inflammatory portion of the immune response system. These mediators include histamine, leukotrienes and prostaglandins.

Short-acting beta-2 agonists are effective bronchodilators for acute asthma attacks. They inhibit the release of mediators of inflammation from mast cells. However, they do not modify the underlying inflammation of asthma nor do they have sufficient duration of action to prevent nocturnal asthma attacks.

Salmeterol is indicated for long-term, twice a day dosing (morning and evening approximately 12 hours apart) in treating and preventing bronchospasm in patients 12 years of age or older with reversible obstructive airway disease. This includes patients with nocturnal asthma who require regular treatment with inhaled, short-acting beta-2 adrenergic agonists. It is also indicated for prevention of exercise-induced bronchospasm in persons in the same age group.

Bronchodilators, including salmeterol as sole therapy, are not sufficient for patients with asthma where bronchial hyperreactivity is due to airway inflammation. These patients are best controlled with inhaled anti-inflammatory agents (corticosteroids) and the "prn" inhalation of short-acting beta-2 agonists for acute attacks.

The drug should not be used in patients with acute attacks whose asthma can be managed with occasional use of short-acting, inhaled beta-2 agonists because it can increase the potential for tolerance to occur. Salmeterol can be used alone or concurrently with inhaled corticosteroids.

Patient Information for Claritin

Claritin is used to relieve the runny nose, watery eyes and sneezing of hay fever and other upper respiratory allergies or other conditions as determined by your doctor.

Unless your doctor has told you differently, Claritin should be taken on an empty stomach with a full glass of water at least 1 hour before or 2 hours after a meal.

You may experience dry mouth while taking Claritin. If you do, suck on hard candy, chew gum or use a saliva substitute.

It is important that you take Claritin exactly as your doctor has instructed. Take it only as needed and do not take more doses than prescribed by your doctor.

Do not take nonprescription cough/cold, asthma, hay fever, sleep aid or diet medicines without first asking your doctor or pharmacist.

If you miss a dose of Claritin, take it as soon as possible. But, if it is almost time for your next dose, skip the missed dose and go back to your regular dosage schedule. Do not take a double dose, unless your doctor has instructed you otherwise.

Do not keep or use outdated medicines.

Keep Claritin at room temperature, in its original, labeled container and out of the reach of children.

In case of accidental ingestion or overdose, call your doctor or poison control center immediately.

Every medicine is capable of producing side effects. Most patients experience few or no problems while taking Claritin. However, be sure to tell your doctor if the following occur: thickening of the bronchial secretions, persistent headache, rapid heartbeat, drowsiness, or any other unusual, bothersome effects.

Adverse effects reported at the 5 percent or higher level are headache (28 vs. 23 percent with the placebo group); upper respiratory infection (14 vs. 13 percent); nasopharyngitis (14 vs. 12 percent); nasal/sinus problems (6 vs. 4 percent); and cough (7 vs. 6 percent).

The recommended dosage regimen for Serevent inhalation aerosol for asthma is 2 inhalations every twelve hours. For exercise-induced bronchospasm, the dosage is 2 inhalations 30 to 60 minutes before exercising. In either instance, the dose will provide protection for up to twelve hours. Patients should not use it more often.

Additional information that can be used in counseling patients using Serevent aerosol inhalation is presented in Table 3.

Nedocromil

Trade Name: Tilade (IP)

Nedocromil is indicated for maintenance therapy to prevent airway inflammation and bronchospasm in patients with mild to moderate bronchial asthma.

There is no evidence to suggest that nedocromil can or should be used in place of cromolyn in patients who have allergic asthma and are stabilized by the latter. Effectiveness to one agent does not predict efficacy with the other.

Another definition for asthma, published in the International Consensus Report by the National Institute of Health in 1992, reads: "Asthma is a chronic inflammatory disorder of the airways in which many cells play a role, including mast cells and eosinophils. In susceptible individuals, this inflammation caused symptoms which are usually associated with widespread but variable airflow obstruction that is often reversible either spontaneously or with treatment, and causes an associated increase in airway responsiveness to a variety of 'stimuli.' This definition helps to explain the role that nedocromil plays in the treatment of asthma.

Therapy for asthma is advancing from simply alleviating bronchospasms to preventing underlying inflammation and teaching the patient to feel that he is an integral part of therapy. This latter concept has been shown to increase compliance and management of the disease.

Treatment of asthma should be aimed at the specific status of the patient.

In controlling immediate asthmatic reactions, the beta-2 adrenergic agonists are best for inhibiting the immediate asthmatic reaction (IAR) and reversing bronchospasm. Cromolyn, nedocromil, and anticholinergics can do this also but to lesser extent. Theophylline has questionable value and steroids are ineffective for reversing IAR.

Table 2

Patient Information for Serevent and Tilade

Serevent and Tilade are used to prevent or reduce asthmatic symptoms (i.e., wheezing, chest tightness, shortness of breath).

The following is one method for administering Serevent and Tilade. Be sure the canister is properly inserted into the inhaler unit. Remove the dust cap and shake the canister well. Unless your doctor has told you otherwise, exhale fully and place the mouth piece into your mouth with your lips closed around it and your tongue flat. As you take a deep breath, squeeze the canister and mouthpiece together at exactly the same time. Continue taking a deep breath and hold it for as long as comfortable. Exhale slowly keeping your lips nearly closed.

Test the inhaler before using it for the first time or if it has not been used for awhile.

Be sure to wait the prescribed time before inhaling a second dose.

It is important that you use this medicine exactly as your doctor has instructed. Do not skip a dose, change the dose, or stop taking it without consulting your doctor.

Since this medicine helps to control your condition, you should continue to use it as long as your doctor tells you, even if you are not experiencing any asthmatic symptoms.

Do not take nonprescription cough/cold, asthma, hay fever, sleep aid or diet medications without asking your doctor or pharmacist.

Keep the mouthpiece clean. After each use, separate the mouthpiece from the dust cap on the medication canister and rinse the mouthpiece with warm water.

When not using the inhaler, store it with the dust cap on the mouthpiece. This will help prevent dirt and dust from getting into the mouthpiece.

If you miss a dose of this medicine, use it as soon as possible. But, if it is almost time for your next dose, skip the missed dose and go back to your regular dosage

doctor or pharmacist for various methods.

For Tilade

Every medication is capable of producing side effects. Most patients experience few or no problems while using Tilade. However, be sure to tell your doctor if the following occur: severe headache, persistent cough or sore throat, nausea or vomiting, or any other unusual, bothersome effects.

For Serevent

Serevent does not replace oral or inhaled corticosteroids: the dosage of these medicines should not be changed and they should not be stopped without consulting your doctor, even if you feel better.

Do not exceed the recommended dose. The bronchodilator action of Serevent usually lasts for at least 12 hours. Therefore, it should not be used more often than every 12 hours.

When using Serevent to prevent exercise-induced bronchospasm, the dose should be administered at least 30-60 minutes before exercise.

On occasion you may experience symptoms even though you have already taken your medication. To treat these acute symptoms, you should use the inhaled short-acting bronchodilator that your doctor may have prescribed for relief of these symptoms. Notify your doctor if shortness of breath persists after the dose, or if the dose fails to provide the usual relief.

Every medication is capable of producing side effects. Most patients experience few or no problems while using Serevent. However, be sure to tell your doctor if the following occur: chest pain, severe dizziness or headache, irregular or pounding heartbeat, or any other unusual, bothersome effects.

Cromolyn, nedocromil and steroids are best at reversing late asthmatic reactions (LAR). Theophylline can reverse them to lesser extent. Beta-2 adrenergic agonists have no activity on LAR. Nedocromil and steroids are best for bronchial hyperactivity, with cromolyn next in effectiveness. Steroids and nedocromil are best for alleviating inflammation of asthma.

Step Care of Asthma

The most recently published step-wise approach to pharmacologic therapy for asthma follows.

Mild asthma. An inhaled short-acting beta-2 adrenergic agonist when needed for wheezing; cromolyn or inhaled beta-2 agonist prior to exercise or antigen.

Moderate, less severe asthma. Cromolyn, nedocromil or inhaled low-dose corticosteroid; inhaled short-acting beta-2 adrenergic agonist when needed for wheezing.

Moderate, more severe asthma. Inhaled, moderate-dose corticosteroid; sustained release theophylline, oral beta-2 adrenergic agonist or long-acting inhaled beta-2 adrenergic agonist; inhaled short-acting beta-2 adrenergic agonist when needed for wheezing.

Table 3

Severe asthma. Inhaled, high-dose corticosteroid; sustained release theophylline, oral beta-2 adrenergic agonist or long-acting inhaled beta-2 adrenergic agonist; inhaled short-acting beta-2 adrenergic agonist when needed for wheezing; oral corticosteroid. After the patient is stabilized, therapy can be stepped down.

Asthma has several components, including early and late release of mediators, that induce the inflammatory response. Their initial release is from mast cells including eosinophils, lymphocytes, macrophages, neutrophils and platelets.

The physiological response to these mediators is bronchospasm, increased permeability of blood vessels in the lungs, increased mucus secretion and hyperactivity of airways to stimuli. Nedocromil inhibits both the early and late portions of the inflammatory response.

The drug is in clinical trials for intranasal administration to treat allergic rhinitis, and intraocular use to treat allergic conjunctivitis. It is not yet marketed in those dosage forms in the U.S.

Adverse reactions and annoying effects associated with nedocromil at the 5 percent or higher level are: unpleasant taste (12.6 vs 3.6 percent for the placebo group); cough (7 vs 7.2 percent); headache (6 vs 4.7 percent); pharyngitis (5.7 vs 5 percent); and bronchospasm (5.4 vs 8.2 percent). The latter shows the effectiveness of the drug.

Get Credit Where Credit is Due

To earn one hour of Maryland State Board of Pharmacy approved continuing education credit for this article, simply complete the CE quiz on page 30.

There is no charge for CE credits for MPhA members! (Non-member's fee: \$5.00)

The most common side effect, unpleasant taste, caused 2.1 percent of the patients to stop using nedocromil. It can be alleviated by using a mouthwash immediately after administration of the inhalation.

The recommended dosage regimen for Tilade aerosol inhalation is to start with 2 inhalations (4 mg) four times a day at regular intervals. After the patient is stabilized, an attempt should be made to reduce the dose to three times a day and then two times a day. The drug must be used regularly, even when there are no symptoms.

Other information that can be used in counseling patients using Tilade aerosol inhalation is listed in Table 3.

MP

The patient education information provided in this series of continuing education articles has been adapted from the Pharmex PALs (patient advisory leaflets). For more information on these leaflets, call (800) 233-0585.

The "MP" Profile

This is the first in a series of interviews with the leaders of the Maryland Pharmacists Association. This month, we profile outgoing student trustee Rhea delRosario.

MP: Tell us something about yourself.

delRosario: I graduated from Towson State with a BS in chemistry in 1992 and then decided to go into pharmacy because I was looking for a stable career. I've been very involved in organizations like MPhA, Kappa Psi, and the Academy of Students of Pharmacy. I've been president of my class. I've worked part-time for NeighborCare's institutional division. I've done rotations at Giant, Church Hospital, and all kinds of places.

MP: You're one of the last BS pharmacists to graduate from the University of Maryland. Why did you not choose to stay and pursue a Pharm.D.?

delRosario: Yes, I'm one of the "Final 47." To be honest, I can't financially afford another year of schooling. I've been in college for almost nine years and the student loans have piled up fast. I don't have any regrets about not pursuing a Pharm.D.. The School has prepared me to be one of the best pharmacists in the country. I also believe that the real learning about pharmacy comes from work and experience and I'm looking forward to being in practice.

MP: Pharmacy's critics have said that we're a dying profession. What do you think about that?

delRosario: How long have people predicted the downfall of pharmacy? I went to a seminar where the speaker read an article saying how pharmacy was doomed and wouldn't be around

in ten years. The article was from 1936. I believe you can't just crumble everytime someone criticizes you or your position. That's the time to fight back, not give up. Of course, pharmacy's going to be different during my career than it was for someone who graduated in 1945. That's to be expected. After all, we can't have progress unless we have change. Pharmacists just have to adapt and change, too. In short, pharmacy isn't going to die, at least not as long as I have anything to say about it!

MP: So, what do you want to do once you graduate?

delRosario: To be honest, it changes with every meeting I attend and every new area of practice I see. I don't think pharmacists realize how lucky we are. I mean, as a chemist, there were no opportunities, no jobs, no nothing unless you had a Ph.D. and had extensive publishing. In May, when I graduate, I'll have so many

choices. Maybe I'll go into retail or maybe industry. Where ever it is, I want to be directly involved with patients and people. That's very important to me.

MP: Any last comments?

delRosario: Anybody know of any good jobs?

MP



Continuing Education Quiz

February 1995 -- Respiratory Agents

This month's questions are taken from the article on recently introduced drug therapies for respiratory agents that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members \$5.00). The completed quiz for this issue must be received by July 31, 1995. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name _____

Address _____

City/State/ZIP Code _____

1. Salmeterol is an analog of:
 - a. albuterol
 - b. isoproterenol
 - c. metaproterenol
 - d. terbutaline
2. The bronchodilation effect of Serevent results from its stimulation of intracellular:
 - a. adenyl cyclase
 - b. histamine
 - c. interferons
 - d. phosphodiesterase
3. The Tilade-induced adverse effect that occurs in the highest percentage of patients is;
 - a. bronchospasm
 - b. cough
 - c. drowsiness
 - d. unpleasant taste
4. Which of the following statements about Claritin is true?
 - a. It blocks peripheral histamine-1 receptors
 - b. It causes torsade de pointes
 - c. It significantly interacts with erythromycin
 - d. It readily crosses the blood-brain barrier
5. A single inhaled dose of Serevent provides bronchodilation that lasts approximately;
 - a. 4 hours
 - b. 8 hours
 - c. 12 hours
 - d. 24 hours
6. Loratidine is a derivative of:
 - a. Benadryl
 - b. Hismanal
 - c. Optimine
 - d. Seldane
7. Serevent is indicated for treating all of the following *except*:
 - a. acute asthma attacks
 - b. prevention of bronchospasm in patients 12 years of age and older
 - c. nocturnal asthma
 - d. prevention of exercise-induced bronchospasm
8. Which of the following is *least* effective for reversing late asthmatic reactions?
 - a. Cromolyn
 - b. Nedocromil
 - c. Salmeterol
 - d. Steroids
9. Which of the following is best for alleviating the inflammation of asthma?
 - a. Loratidine
 - b. Nedocromil
 - c. Salmeterol
10. The manufacturer of Claritin recommends that patients be advised to take the tablets:
 - a. with food
 - b. on an empty stomach.

CLASSIFIED ADS

Positions

PHARMACISTS Earn extra money working around your schedule. Seeking retail, hospital, and institutional pharmacists for prn employment. Enjoy flexibility, an excellent pay rate, and cash bonuses. Join *PharmaSTAT!* For information call (410) 659-STAT.

PHARMACIST WANTED. Due to recent expansion, Revco is actively seeking full-time and part-time pharmacists in various locations thru out Maryland. We offer a complete benefit package including medical, dental, life and disability insurance, profit sharing, Rx bonus and continuing education. Our computer system is state-of-the-art. Call Brian Chivers at (301) 893-3704.

PHARMACISTS/MANAGERS WANTED Thrift/Treasury Drug, a subsidiary of JC Penney Company, a Fortune 100 company, has career opportunities available in the Cumberland, MD area for staff pharmacists and pharmacists looking for a chance to enter into the Pharmacy Management field. These positions feature: excellent starting salary (with bonus for management), comprehensive benefit package including dental, profit sharing, and a 5-day workweek with every other weekend off. Contact Bill Kerrish at (800) 284-7438, extension 8374.

PART TIME PHARMACIST available. 15-20 hours/week. Experienced in all phases of community pharmacy. 3 PM computer experience. Call (410) 484-5527.

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Services

20% DISCOUNT on awards, plaques, trophies, and engraving to MPhA members. Call Rudy Winternitz, P.D. at Washington Trophy Center, (202) 966-1255.

PHARMACISTS REHABILITATION COMMITTEE For private, confidential referrals call (410) 727-0746 or (410) 706-7513.

Rx LICENSE TAGS are still available! A special benefit "for members only" that costs only a nominal fee. If interested, call Mary Ann at the MPhA offices toll-free, (800) 833-7587.

Miscellaneous

WANTED Baltimore pharmacy artifacts and objects (especially local pharmaceuticals, advertising posters and counter top displays) for Baltimore Museum of Industry. Call (410) 727-4808, extension 4.

Business Opportunities

INFUSION BILLING SPECIALIST. Inexperienced Billers + Employee Turn Over = \$\$ Problems. We are "the" experts in problem reimbursement. Over 12 years experience in billing with 8 years in the infusion field. We take the hassles out of reimbursement. Call now for prompt, professional billing service. Call (410) 391-1903 or 426-8711.

PHARMACY FOR SALE located in a medical building. Good location with parking. Medical supplies and surgical support stockings account for 65% annual income. This store has a lot of potential for the right person and it is priced for a quick sale, only \$175,000. Phone (301) 474-5151.

Placing an Ad

Have something to sell, rent, or trade? Need a pharmacist? Looking for a new position? MPhA members can place a classified ad in *The Maryland Pharmacist* for free. MPhA will remove member ads after six months unless otherwise notified by the member. Non-members may also place a classified ad. The ad placement charge is \$10 for a maximum of 50 words plus 50 cents per word greater than 50. To place an ad, call MPhA at (800) 833-7587.

Vacation Ideas

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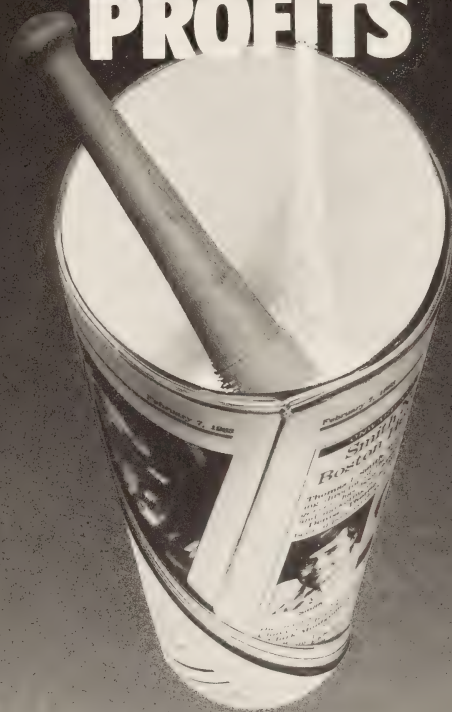
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In the March Issue...

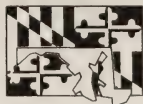
1995 ELECTIONS FOR THE MARYLAND STATE BOARD OF PHARMACY!

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NEWSLETTER

The Maryland Pharmacists Association

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MPhA Calling.... NOT

It has come to our attention that an out-of-state placement service has been calling Maryland pharmacies asking for the names and addresses of their pharmacists and technicians. The caller(s) identify themselves as MPhA employees and explain that they are putting together a seminar. If the pharmacist hesitates and asks to call back, the caller gives a fictitious name and telephone number. The callers are *not* from PharmaSTAT or Pharmacists: PRN, both reputable companies that have a long-standing relationship with MPhA.

MPhA staff, and occasionally a PEP student, will only call to verify information we already maintain (addresses, FAX numbers, etc.). Even these calls are rare. Most of our communication is via mail or FAX.

If anyone calls identifying themselves as an MPhA representative and is asking for information, ask them to put it in writing or send you a FAX. Then give us a call at (800) 833-7587 to verify their legitimacy.

Welcome New Members

The following pharmacists joined the MPhA in January:

- Charles Bates•
- Dorothie Briggs•
- Scott Plafker•
- Karen Smith•
- Shu-Yu Tsai•
- David Vaxmonsky•

February 1995

The MPhA Newsletter is published monthly except during the months of July and August when the issues are combined. For information about any article contained herein, contact MPhA at (410) 727-0746 or toll-free at (800) 833-7587. President: Arnold Davidov, P.D.; Chairman, Board of Trustees: Howard Schiff, P.D.; Production Manager: David Miller, P.D..

Medicaid Fees Slashed

Part of Governor Glendenning's 1996 state budget includes a \$1.8 million reduction in Medicaid payments to pharmacies. That reduction, of 40 cents per prescription, is scheduled to become effective on July 1, 1995.

"MPhA has put together a series of proposals for the Governor and the Department of Health and Mental Hygiene that will save at least \$1.8 million *without* reducing pharmacy reimbursement," says Health Care Policy and Legislation Committee Co-chairman **Phil Marsiglia**. "Our proposals range from simple cost-savings ideas like eliminating the printing and distribution of red and white Medicaid prescription blanks, passing fairness in drug pricing legislation to help save the State more money on drug product costs, and exploring a preferred product list to maximize the amount of rebates paid to Medicaid by pharmaceutical manufacturers."

MPhA will be meeting with State officials to present these proposals. While the \$1.8 million budget reduction cannot be removed from the budget, legislators and the Administration can obtain the money from alternative sources. Details will be forthcoming.

Legislative Update

After a relatively slow start, the Maryland General Assembly took off in early February. Currently, MPhA is tracking more than 60 pieces of legislation affecting pharmacy, controlled substances, insurers, managed care, and pharmaceutical pricing.



"MPhA has three legislative priorities this year," says Health Care Policy and Legislation Committee Co-chairman **Ernie Testerman**. "They are to continue our fight for fair and open access to prescription benefit programs, to seek an end to discriminatory pricing, and to overhaul the Board of Pharmacy nominating procedure to assure adequate

practice representation." A complete overview of the most important legislation affecting pharmacy is enclosed in this month's newsletter. MPhA members interested in specific legislation, or who want an actual copy of any of the listed bills, are asked to contact the Association headquarters at (800) 833-7587.



The Board of Pharmacy reminds all pharmacists that *it is your responsibility* to renew your license every other year by September 30! Employers should have ensure that all pharmacists working for them have current licenses. Practicing pharmacy without a current license is a serious offense.



Pharmacy Tragedy

A serious dispensing error was allegedly committed by a staff pharmacist at the Anne Arundel County Medical Center in late January. Apparently, heparin flushes for neo-natal use were compounded with an opiate derivative. Three infants received the improperly dispensed medication.

Since no pharmacist is perfect, dispensing errors are bound to occur. Therefore, every pharmacist should carry *personal* pharmacist liability insurance. While many employers maintain liability insurance on their pharmacists, that policy may or may not protect you as an individual from being sued directly. Both APhA and NARD have affiliations with insurers that offer competitive rates (\approx \$120/year for employee pharmacists). Call APhA at (202) 628-4410 or NARD at (800) 544-7447 for information.

1995 Association Elections

MPhA Nominating Committee Chairman **Jim Tristani** announced the candidates for the upcoming Association elections at the February meeting of the MPhA Board of Trustees. Once approved by the House of Delegates during the Mid-Year Meeting, a ballot will be distributed to all members for voting in March.

The nominees for officer and trustee positions are:

President Elect: Ernest Testerman and Ellen Yankellow

Vice President: Alisa Billington and Jean Freels

Treasurer: Ron Sanford and Martin Yankellow

Trustee Seat 1: Abigail Lagman and Tim Lubin

Trustee Seat 2: W. Irving Lottier and Robert Martin, Jr.

Trustee Seat 3: Murhl Flowers and Marrocco

Trustee Seat 4: Doug Haggerty and Phil Marsiglia

New Board of Pharmacy Exec

Norene Pease has been announced as the new executive director for the Maryland State Board of Pharmacy. Pease, who takes Roslyn Scheer's position, started with the Board in mid-January. She has fifteen years of experience managing public health programs in a variety of settings, including a hospital and county, regional and state health planning agencies.

Ms. Pease brings an interesting mix of health care provider and state administration experience to her new position. Her educational background includes masters' degrees in business administration and counseling psychology. She has previously served as the Administrator for the State Board of Morticians.

MPhA welcomes her and looks forward to a long and cooperative relationship.

Coverage Questions

Any pharmacist that owns, operates or works for a small business knows how confused purchasing health insurance has become under Maryland's 1993 Health Care and Insurance Reform Act. Help is now available. Answers to questions related to the standard benefit, copayments, exclusions, who must offer what, etc. can be found in a new booklet called *Maryland Comprehensive Standard Benefit Plans* published by the Maryland Insurance Administration. The booklet is available by calling the Insurance Administration's Consumer Services Section at (800) 492-6116 or (410) 333-3288. Copies may also be obtained by writing to: Consumer Services Section, Maryland Insurance Administration, 501 St. Paul Place 11th Floor, Baltimore, MD 21202-2272. All Maryland pharmacists



are invited to attend and participate in the **Dean's Colloquia**, a series of lectures on current issues affecting the profession. All events are free and open to the public and are held in Davidge Hall on the University of Maryland at Baltimore campus. The series is underwritten by Glaxo, Marion Merrell Dow, and the David Stewart Associates. Upcoming programs include:

March 28

Pilot Research Results: Patient Education Using the USP/DI "Visualized About Your Diabetes"

Heidi M. Anderson-Harper, Ph.D.

Auburn University

April 11

Nuclear Pharmacy Practice PLUS Care

Stanley M. Shaw, Ph.D.

Purdue University

1995 Legislation Affecting Pharmacy

Bills Introduced in the Maryland House

February 1995

| Bill | Title | Sponsor | Description | MPhA Position |
|---------|--|---|---|-------------------|
| HB 351 | HMOs - Coverage for Off-Label Uses of Drugs | | Prohibits HMOs from denying coverage of drugs because the use is not FDA approved. An expansion of last year's law. | Support |
| HB 399 | Health Insurers - Standards for Provider Panels | Hurson | Requires all HMOs, insurers, and third-parties who use provider panels to publish and provide due process to providers. | Support |
| HB 513 | Fairness in Drug Pricing | Barve, Goldwater, Krysiak, Boston, Exum | Requires manufacturers to provide equal access to discounts/prices. | Support |
| HB 581 | HMOs - Liquidations - Priority of Claims | Elliott | Provides that providers are second group (after subscribers) to be paid when an HMO goes bankrupt. | Support |
| HB 724 | Patient Access Act | Barve, Kach, Boston, Kirk, et. al. | Requires HMOs and insurers who use panels of providers to have published criteria (due process) and fair payment systems for out-of-panel providers. | Support |
| HB 746 | Quality Health Care Act | Hurson | Requires all payors (HMOs, insurers, administrators) to permit any willing provider to participate in provider panels. | Support |
| HB 792 | Health Care Networks | Hurson | Requires all insurers, HMOs, and other payors who use provider networks to have published criteria and processes in place for reviewing provider applications | Support |
| HB 805 | MD Pharmacy Assistance Program | Departmental | Extends MPAP (and MPhA's involvement in maintenance formulary) until June 30, 1996. | Support |
| HB 933 | Terminal Illness - Physician Aid in Dying | Dembrow, Genn | Enables patients to seek physician assisted suicide, establishing certain protection to physicians. Does not mention pharmacists or pharmaceuticals. | No Position |
| HB 994 | Health Networks - Discrimination Prohibition | Oaks | Prohibits health networks from discriminating against providers based on age, sex, race, religion or national origin. | Support |
| HB 1017 | Due Process Termination Hearing | Dembrow | Requires managed care carriers to guarantee that a provider will not be terminated except for breach of contract with a hearing. | Support |
| HB 1120 | HMOs - Review of Bids for Pharmacy Services | Guns, Weir | Requires that HMOs provide a written explanation for denying participation in a pharmacy provider panel. | Support |
| HB 1164 | Insurers - Amendments - Approval by Commissioner | Harrison, Branch | Expands current requirement that non-profit health service plans obtain Insurance Administration approval for all contracts to HMOs and for-profit insurers. | Support |
| HB 1199 | Home Medical Equipment Providers | McHale | Puts non-pharmacy DME providers under the purview of the Board of Pharmacy and requires them to pay a license fee to the Board. | Support and Amend |

1995 Legislation Affecting Pharmacy

Bills Introduced in the Maryland Senate

February 1995

| Bill | Title | Sponsor | Description | MPhA Position |
|--------|--|-------------------------------------|--|-------------------|
| SB 275 | Board of Pharmacy Membership | Hollinger | Revises Board appointment process to include specific seats for practice and minorities. | Support |
| SB 290 | Commercial Law - Fairness in Drug Prices | Dorman, Astle, Della, Derr, Trotter | Requires manufacturers to provide equal access to discounts/prices. | Support |
| SB 329 | Board of Pharmacy - Rehab Committee Funding | Hollinger | Emergency bill. Allows Board of Pharmacy to provide funding to Rehab Committee. | Support |
| SB 446 | Home Medical Equipment Providers | Hollinger | Puts non-pharmacy DME providers under the purview of the Board of Pharmacy and requires them to pay a license fee to the Board. | Support and Amend |
| SB 449 | Patient Access Act | Hollinger, Della, Boozer, et. al. | Requires HMOs and insurers who use panels of providers to have published criteria (due process) and fair payment systems for out-of-panel providers. | Support |
| SB 573 | Sales and Use Tax - Medical Equipment | Amoss, Collins | Clarifies definition of medical equipment exempted from sales tax. | Support |
| SB 590 | Health Networks - Discrimination Prohibition | Young, Trotter | Prohibits from health networks from excluding providers based on age, sex, race, national origin or religion. | Support |
| SB 638 | Health Care Networks | Dorman, Young | Due process provisions requested from the Governor's Task Force on Community Health Networks. | Support |
| SB 694 | Medicaid - Expansion of Managed Care Plans | Hollinger | Requires Medicaid to enroll all recipients into managed care plans. | Oppose |

For a copy of any of these bills, please call the MPhA offices at (800) 833-7587 or FAX us a request at (410) 727-2253.

Upcoming Health Events

Telephone numbers are provided for additional information and promotional materials.

March

| | |
|--------------------------------|----------------|
| Cataract Awareness Month | (708) 843-2020 |
| Hemophilia Month | (212) 819-8180 |
| Mental Retardation Month | (817) 261-6003 |
| National Kidney Month | (800) 622-9010 |
| National Nutrition Month | (800) 745-0775 |
| Nutrition Awareness Month | (404) 320-3333 |
| Red Cross Month | (202) 639-3185 |
| Rosacea Awareness Month | (708) 382-7404 |
| Save Your Vision Week (5-11) | (314) 991-4100 |
| Poison Prevention Week (19-25) | (301) 504-0580 |

April

| | |
|-----------------------------------|----------------|
| Alcohol Awareness Month | (212) 206-6770 |
| National Anxiety Month | (201) 763-6392 |
| Stress Awareness Month | (410) 732-1900 |
| Organ & Tissue Donor Week (23-29) | (800) 622-9010 |

Wyeth-Ayerst Product Coverage

According to Pharmacy Assistance Transmittal 19, issued at the end of December 1994, Wyeth-Ayerst has discontinued a rebate agreement that affects coverage of some of their products.

Except for Quinidex, Cordarone, Mysoline, Premarin, and Phospholine Iodide, Wyeth-Ayerst products with NDC codes 00008, 00031, 00046 are no longer covered under Pharmacy Assistance.

Please note that this change has no affect on the Medical Assistance Program. For questions, contact Frank Tetkowski at (410) 225-1459.

Post Scripts

- R Bristol-Meyers Squibb has calendars available that list all major pharmacy events for the coming year. See your local BMS representative or call MPH's liaison, Ron Poppel at (410) 956-5577.
- R Financially strapped patients can now take advantage of Merck's new Access program for Mevacor 40mg. Access, part of Merck's Vital Interests program, combines pharmacies and the Merck/Medco PAID prescription third-party administrator. To enroll in Vital Interests or Access, or to get more information, call (800) 557-5666.
- R **George Dukes**, chairman of the Department of Pharmacy Practice at the University of Maryland School of Pharmacy, has been chosen as the 1995 President-Elect for the American College of Clinical Pharmacy. He will be installed at the upcoming ACCP meeting in Washington DC and will assume the Presidency the following year in Nashville.

OTC Pamphlets Available

Millions of Americans read below high school level, and many find reading labels on products, including OTCs, difficult to understand. To help them, the National Consumers League has produced "Take Care With...." a series of six easy-to-read brochures on self-medication with OTC products. The pamphlets focus on allergy, asthma, cough and cold, antacid, pain and children's medications.

Each of the brochures highlights the importance of consulting a pharmacist for questions about OTCs. Using large print, simple words, and colorful graphics, the brochures convey a great deal of information to a population that has too often be disregarded. Produced through a grant from the Nonprescription Drug Manufacturers Association, the National Consumers League plans to distribute more than a million of the brochures nationwide. For a set of six brochures, send \$2 to cover postage and handling to the National Consumers League, 815 15th Street NW, Washington DC 20005. For bulk requests, contact Stepayne Walker at (202) 639-8140.



APS Reimbursement Change

Arnold Blaustein of Associated Prescription Services, a Value Health company, has announced that effective March 1, 1995, reimbursement rates for the following APS funds will change: 029, 031, 051, 058, 113, 138, 139, 140, 168, 171, 172, 188, 190, 191, 216. The new reimbursement rate is the lesser of AWP-12% or usual and customary. The dispensing fee is \$2.25 with a 50 cents bonus for dispensing generics. For answers to questions, call (410) 602-3339.



Maryland Pharmacy Event Calendar

March 9 "1995 Peter Lamy Memorial Lecture", 8:30 am, UMAB's Westminster Hall. Call (410) 706-5893.

March 9 MPhA Board of Trustees Meeting, MPhA Headquarters, 7:00 pm.

March 9 MSHP Monthly Meeting, "Pain Control," 6:00 pm, St. Joseph's. Call (410) 752-3318.

March 18-21 APhA Annual Convention, Orlando, Florida. Call APhA at (202) 628-4410.

March 19 AZO Fritz Berman Memorial Seminar, "Prostate Cancer and Incontinence", Pikesville Holiday Inn

March 19-25 National Poison Prevention Week. Call Lisa Booze at the Poison Center, (410) 706-7604 for details.

March 22 Eastern Shore CE Program, "Anti-Anginal Therapy," Rustic Inn, Easton. 8:00-10:00 pm.

March 26-28 NARD Legislative Conference, Washington, DC. Call NARD at (800) 544-7447.

March 27-31 NARD Fitting School/Exam (OTC), Anaheim, CA. Call NARD at (800) 544-7447.

March 28 UMAB/Rx Alumni Association Meeting, 8:15 pm, Room 740, School of Pharmacy.

April 1 UMAB/Rx Open House for Prospective Pharmacy Students, (410) 7076-0756 to register.

April 9 AZO CE Program, 9:30 am, Pikesville Holiday Inn. Call David Banks at (410) 465-5683.

April 20 MPhA Board of Trustees Meeting, MPhA Headquarters, 7:00 pm.

April 24-25 NARD Fitting School/Exam (Camp), Milwaukee, WI. Call NARD at (800) 544-7447.

April 25 UMAB/Rx Alumni Association Meeting, 8:15 pm, Room 740, School of Pharmacy.

April 26 Eastern Shore CE Program, "Tuberculosis," Rustic Inn, Easton. 8:00-10:00 pm.

May 8-12 NARD Fitting School/Exam (OTC), Dallas, TX. Call NARD at (800) 544-7447.

May 8-9 NCPIE 10th Conference on Prescription Medicine Information, Washington, DC. (202) 347-6711

May 18 MPhA Board of Trustees Meeting, MPhA Headquarters, 7:00 pm.

May 21 AZO CE Program, 9:30 am, Pikesville Holiday Inn. Call David Banks at (410) 465-5683

May 23 Washington County CE Program, American Legion, 7:00 pm. Call Chris Brown at (301)

June 4 Washington County Golf Outing and CE. Call Chris Brown at (301)

June 18-21 MPhA Annual Convention, A New Frontier for Pharmacy, Ocean City

July 13-16 AmeriSource "Celebrate the Music" 9th Annual Trade Show, Opryland Hotel, Nashville, TN

NEWSLETTER

The Maryland Pharmacists Association

650 Lombard Street

Baltimore, Maryland 21201



MARYLAND PHARMACIST

March 1995

Vol. 71, No. 3

The 1995 Board of Pharmacy Elections

- Counseling Requirements
- Statements from Board Nominees
- Relieved Pharmacist
- Hospitals and Health Systems
- Filling Too Fast



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MARYLAND PHARMACIST

The Official Publication of The Maryland Pharmacists Association

March 1995

4 President's Commentary

MPHA President Arnold Davidov's new computer software gives him something to think about.

5 Mandatory Patient Counseling

Two years after enactment, Maryland's patient counseling law still creates questions.

8 Litigation Update

Columnist David Brushwood reviews a case where the number of prescriptions filled by a pharmacist was reason for a mistake.

9 The 1995 Board of Pharmacy Elections

MPHA Nominating Committee Chairman Jim Tristani provides instructions for completing your ballot to help select the next member of the Maryland State Board of Pharmacy. A ballot and return envelope is enclosed with this issue for all pharmacists licensed in Maryland.

10 Statements From the Board Nominees

Each of the candidates for the Board of Pharmacy present their qualifications and vision for the Board.

19 Hospitals and Health Systems

The first in a quarterly bulletin from the Maryland Society of Hospital Pharmacists.

21 Maryland's Entrepreneurs

Glenn Lichtman's frustration about long hours and no relief gave him an idea for a new business.

24 Continuing Education

This month we present Part V in our ongoing update of new drugs and drug therapies. Featured are antiepileptics. Don't forget to complete the CE quiz on page 30 for credit! It's *free* for all MPHA members.

The Maryland Pharmacist (ISSN 0025-4347) is published monthly by the Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201-1572. Annual subscription - \$10. Single issue copy, \$1.50. Members of the Maryland Pharmacists Association receive the publication as part of their annual membership dues. Entered as second class matter at Baltimore, Maryland and additional mailing offices.

Articles and editorials that appear do not necessarily reflect the official positions of the Maryland Pharmacists Association and may contain views and opinions for which the authors hold sole responsibility.

Postmaster: Send address changes to MPHA, 650 West Lombard Street, Baltimore MD 21201.

Advertiser's Index

Whenever the opportunity arises, please thank them for their support.

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President's Commentary

We and My (Automated) Shadow....

Ever seen one of those old 1950's science fiction "vision of the future" movies on the late show? The kind where computers have created a utopia, leaving the human race to pursue art, beauty, and knowledge? The ones where the computers either break down take over the world and the humans have to turn them off and learn to do for themselves all over again?

Well, while listening to National Public Radio the other day, I heard of a new computer development that makes me wonder if maybe those sci-fi movies weren't too far off the mark.

Apparently, a New England professor of music has programmed his computer with all of the Bach two- and three-part Inventions. He then wrote a program, using a form of artificial intelligence, that has the computer review the patterns in these musical works, reinterpret the patterns, and create completely new pieces of classical music *in the style* of Bach. What I thought curious was the professor's statement that his program (and his computer's "creative" works) is meant only to help musicians better understand composition. He does not intend for these computer generated works to ever be published or played by "real" performers.

Perhaps it was only a coincidence, but my pharmacy's computer software had just been updated. The new program now allows us on-line access to more detailed drug/drug interaction information, more drug utilization review criteria interpretation, and space to input patient counseling documentation. As with any new system, it's taking all the pharmacists in our practice to recognize and realize the software's increased capabilities.

After about two weeks of working with it, I feel much more comfortable in patient counseling and talking to health care providers when I am faced with a potential problem. Before, our computer would alert us to a drug interaction but we had to actually stop and look it up in one of several reference books. Our new system gives us all the facts we need to make a decision right on the screen.

As I mentioned, our system also includes a major area for patient counseling tracking and documentation. So far, I have used this for two purposes. One, I now have the ability to document patient counseling in a user friendly atmosphere. It is not difficult to use and takes a relatively short time to type in a few notes on what I have discussed with a patient and substantiate any actions taken on that patient's behalf. The input into this screen is automatically saved as part of the patient's profile and can be reviewed at a later time by me or by another

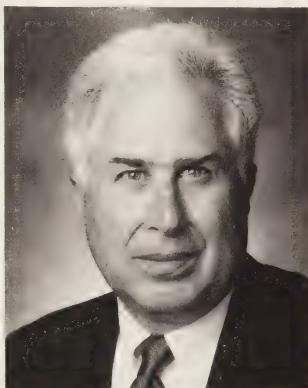
pharmacist. Second, I can also use the patient counseling screen to document my conversations with health care providers about drug and disease related problems. All in all the new software has helped to make me a better pharmacist and has enabled me to more involved with my patients.

But even though I'm happy with all my computer's new capabilities, I wonder if maybe I'm running the same risks as those sci-fi folks. Will there come a time in pharmacy where the computers can handle all the work? Will there come a time when pharmacists, who have had nominal patient interaction and done nothing but hover over their computer screens, can be replaced by artificial intelligence. Already,

computers and robotics are eliminating the need for dispensing pharmacists and technicians in mail-order facilities and some major hospitals. Are we far from the time when a "smart" computer can handle patient questions and provide patient counseling?

I don't know. All I can do is hope that every pharmacist makes him or herself indispensable to patients and consumers. I can only hope that pharmacists will recognize that their computers are a tool to give them more time for patient interaction, not less.

If not, we might just end up like that musical computer program, writing symphonies that nobody will ever hear.



Arnold Davidov, P.D.
1994-1995 MPbA President

Mandatory Patient Counseling

An Opportunity for Patient Interaction

Melvin Rubin, P.D., Secretary and Commissioner
Maryland State Board of Pharmacy

Often a new law is passed because legislators see or perceive a problem which they want to address. Other times, state laws are the result of a mandate by a federal agency.

The latter is the case with the "counseling law" which went into effect in Maryland in 1993. Congressional action through the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) required that state Medicaid agencies must have pharmacist counseling for recipients or risk losing funds.

Maryland's law sets the minimum requirements for pharmacist interaction with patients. Title 12 of the Maryland Health Occupations Article -- where our pharmacy laws appear -- now includes paragraph 512 "Consultation with Medical Assistance Recipients and Caregivers: Records."

In order to be in compliance with the Federal mandates, the Medical Assistance Programs surveys recipients to ask if they did indeed receive an offer to counsel and, when appropriate, the actual counseling. The Division of Drug Control on routine inspections checks to see how pharmacists are complying.

The law requires that the pharmacist *offer* to discuss the medication dispensed on new prescriptions either by directly asking the patient if they want counseling, or by two of four other options -- a sign posted, a note on the prescription bag, a note on the prescription container, or a telephone communication.

Of course, nothing in the law prohibits pharmacists from practicing good pharmaceutical care by starting the conversation with the patient and telling them about the medicine rather than just offering to answer questions.

Certainly many pharmacists were counseling patients long before this law went into effect, and the numbers have increased since. Perhaps the only information needed might be "this is the same medicine that you had before - did it help you before? Did you have any problems with it?" Perhaps the conversation should start with how the patient should take the medicine, then add any information that is appropriate.

The law itself does give you a good starting point. It specifies that you *may* include:

- Name and description of the medicine.
- Route, dosage form, dosage, route of administration, duration of therapy.
- Special direction and precautions for preparation, administration, and use by the patient.
- Common severe side or adverse effects or interactions and therapeutic contraindications.
- Techniques for self-monitoring drug therapy.
- Proper Storage.
- Prescription refill information.
- Action to take in the event of missed dose.

Maryland's law was specifically written so as not to mandate that **all** of the above be discussed. Getting the medication to the patient the same day is important too and the Board realizes that there are times when you will only be able to discuss the most germane of the topics.

On the other hand, a patient who has waited 10 or 15 minutes for the medicine on top of an hour or more wait at the physician's office, may not receive

necessary information if your question is "Do you want to be counseled?" or worse yet -- "If you can wait until I'm not so busy I will be glad to counsel you." This might satisfy the law but not good pharmaceutical practice. There could be a time when you have to say "Can I call you later at home to discuss some points that will help make this medication work better for you?" No harm in that.

There is no obligation for you to keep a log that you offered to counsel, but you might consider doing it for your own protection. If Medicaid asks a recipient a month or more later whether they remember being counseled and they say no, you may have to defend yourself. Here's a suggestion: add a line to your third party signature log saying that the patient acknowledges the offer to council and have them sign it. On deliveries or when a neighbor or child picks up the medicine, use the space to write an explanation yourself, including how you made the offer to counsel (notes, sign, phone etc).

The law requires that the pharmacist make a reasonable effort to obtain, record, and maintain, at the individual pharmacy at least the following information regarding a Medical Assistance recipient:

- Name, address, telephone number, date of birth or age, and gender.
- Individual history when significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and
- Pharmacist comments relevant to the individual's drug therapy which may be recorded either manually or electronically in the patient's profile. Computer programs may need to be written to give you enough space to record the necessary information. Most systems hid their heads in the sand while this law, which has a genesis in the late 80's was advancing along to final status. Computer systems should have long ago been ready to allow the pharmacist ways to accumulate this information and other medical information needed to properly treat the patient. Some are now belatedly catching up.

Provider Care

Provider helping Provider

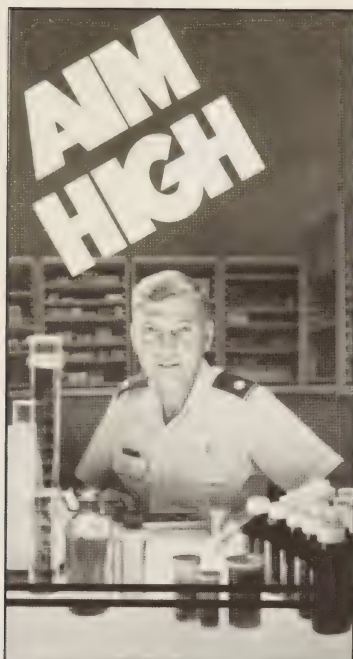
Provider Care offers a safe, confidential, "outside the system" place for pharmacists to address difficult and sometimes painful personal issues. Dr. Paul Terpeluk, a physician, family therapist and addictionist, has worked closely with physicians, nurses and pharmacists in addressing many of these concerns. He offers the following :

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- ◆ Grief work
- ◆ One-half day intensive individual/family sessions (*Retreat Center at Gobbler Hill Farm*)
- ◆ Full day individual/family retreats (*Retreat Center at Gobbler Hill Farm*)

Provider Care has offices in Annapolis, Chestertown, Easton and Glen Burnie. Additionally, *Provider Care* operates the *Retreat Center at Gobbler Hill Farm* on Maryland's tranquil Eastern Shore.

For further information or to arrange for a *confidential* meeting, please call:

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The law again provides leeway in record keeping stating that the pharmacist must only "make a reasonable effort to obtain, record, and maintain, at the individual pharmacy" listed minimal information about Medical Assistance patients. This includes:

- Name, address, telephone numbers, date of birth, gender.
- Individual history when significant, including disease states.
- Known allergies and drug reactions, and a comprehensive list of medications and relevant devices.
- Pharmacist comments relevant to the individual's drug therapy.

Refills are specifically excluded from the provisions of the law, but, of course, you are not limited from counseling on refills.

If this law requires -- and better yet -- encourages pharmacists to be conversant with the patient there is perhaps a hidden advantage for everyone. In simpler times in the past, when "Doc" knew everyone by their name as well as knowing their families and being considered a friend as well as a medical professional, the patient more often saw the pharmacist as a human being who has

helped them many times. The relationship made the patient an understanding person if a minor error occurred and could be easily handled. A pharmacist who does not establish a relationship with patients is probably more likely to be reported to the Board of Pharmacy or an attorney for anything that is less than perfect, even if not a harmful error.

Perhaps many of you who have begun talking more to patients have already come to realize how much friendlier they became. And, as an extension of this thought about communications, we have seen that when an error does occur, the pharmacist who handles the situation in a caring manner is less likely to be reported to the Board. Explaining the prescription to the patient offers you a last chance to double check yourself. If the patient seems confused when you tell him what the medicine is for, check it out.

I am sure that many of you have heard patients complain that they miss the physicians who took time to know them and talk to them. Use the requirements of the Mandatory Patient Counseling law, expand them as much as your time permits, and let them know that Doc still looks after them -- at least "Pharmacist Doc" does.

MP

Litigation Update

28.5 Scripts Per Hour is OK... Maybe...

A Louisiana Court of Appeals panel has recently upheld a verdict in favor of a pharmacy and pharmacist who were sued as the result of the pharmacist having allegedly placed two dispensed medications in the wrong vials.

The patient, a 73-year old woman, was given prescriptions for Restoril and Prozac, and these were filled at the defendant pharmacy. The woman later received a refill of both medications, and shortly thereafter began suffering symptoms of an overdose of Prozac. Her physician determined that the bottle of Restoril contained Prozac, and that the overdose was due to the directions for Restoril, which had instructed to take more tablets than the instructions for Prozac.

After a trial, the jury returned a verdict for the defense, evidently believing that the mix-up occurred in the woman's home rather than at the pharmacy. The appellate court reviewed this verdict to determine whether it was clearly wrong based on the evidence.

In a section of the legal opinion that focused on workload, the appellate court noted that three full-time pharmacists one part-time pharmacist were employed at the pharmacy. The court stated that the pharmacy filled 800 prescriptions per day, and calculated that the average number of prescriptions filled per hour for each pharmacist was 28.5, or one prescription every 2.1 minutes.

The pharmacist who filled the woman's prescriptions stated that this workload took a great deal of concentration, and if interrupted during the process, he would have to start over again. The pharmacist stated that he was often interrupted to

answer questions or to speak on the telephone. The pharmacist admitted that he had made errors in the past in putting the wrong medication in the wrong vial, but stated that due to his checking procedures, this has never resulted in giving a patient the wrong medication.

An expert witness, who was a pharmacist, testified that "To fill prescriptions at that rate for eight hours requires intense concentration, and there is a high likelihood of making a mistake especially if there are other interruptions."



David B. Brushwood

Nevertheless, the jury verdict in favor of the defendants was upheld on appeal. Perhaps had the patient been younger, or not been so confused about what occurred (her testimony was very contradictory), the court and jury would have been less certain that the pharmacist's procedures were sufficient to prevent all error. This is the first case against a pharmacist to raise workload as a basis of liability. It will certainly not be the last, and the next case will perhaps not raise questions of the patient's own culpability.

MP

Based on: *Bookman v. Ciolino*, 1994 Westlaw 696732 (La. App. December 14, 1994). All Rights Reserved. © 1994, David B. Brushwood. Reprinted from *Dickinson's Pharmacy*.

The 1995 Board of Pharmacy Elections

*James Tristani, P.D., President-Elect
Maryland Pharmacists Association*

In 1992, the Maryland General Assembly changed the laws governing the appointment of pharmacists to the Maryland State Board of Pharmacy. The new laws now enable all pharmacists in the state to have the opportunity to nominate and vote for the person they feel would best represent their interests as a Board Commissioner.

Last fall, the Maryland Pharmacists Association began the lengthy process of obtaining nominations from individuals interested in serving on the Board of Pharmacy. A call for nominations was issued to pharmacists through the MPhA newsletter and by flyers. Eight pharmacists were nominated.

Each of these eight pharmacists were invited to speak and present their credentials and opinions before the pharmacy community at the February 1995 MPhA Mid-Year Meeting in Annapolis. They also wrote a brief description of their goals and opinions for you, the voting pharmacist, so that you could best judge their qualifications as a Board of Pharmacy Commissioner.

It is now your turn to take part in the selection process!

Pharmacists licensed and residing in Maryland received a ballot and return envelope with this month's issue of *The Maryland Pharmacist*. On the next several pages appear the written statement from each of the eight candidates. Please review each of the candidates' statements and then select up to three names of those candidates you feel would be best qualified for the position. Return your ballot in the provided envelope by April 1, 1995.

Once all ballots have been returned, the MPhA Canvassing Committee will tally the votes. The names of the three candidates who receive the most votes will be submitted to the Governor. The Governor, by law, makes the final selection from the submitted list.

Each of the eight candidates presented here represent some of the best and brightest of our colleagues. I believe that any of them would be an exceptional addition to the Maryland State Board of Pharmacy.

Voting Instructions

1) Select up to three (3) different names by *checking* the box next to the last name of the candidate on the enclosed ballot. You may vote for less than three names. Your ballot will be invalidated if you check more than three (3) names.

2) Return your completed ballot in the provided return envelope to the Maryland Pharmacists Association. Your ballot must be postmarked no later than April 1, 1995.

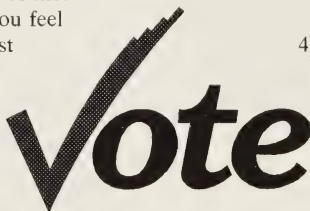
3) A Canvassing Committee of two MPhA members and two non-members will count the ballots.

4) The names of the three candidates who receive the most votes will be sent to the Governor in order of vote count.

For example, if

Candidate A receives 100 votes, Candidate B receives 200 votes, and Candidate C receives 225 votes, the list will appear like this: Candidate C, Candidate B, Candidate A.

5) The Governor will then select the candidate to be appointed to the Board of Pharmacy. The list of candidates sent and the final appointment will be reported to the pharmacy community in an upcoming publication of the Maryland Pharmacists Association.



Vote

MP

Phyllis M. Bartilucci

6235 KERRICK DRIVE
LAPLATA, MARYLAND



GRADUATED

1975, ST. JOHN'S UNIVERSITY

PRACTICE

Hospital

If appointed to the Board of Pharmacy, I will bring a unique perspective on the practice of pharmacy. While my career has primarily been in the hospital arena, culminating in my present position as Director of Pharmacy at Physicians Memorial Hospital, I have had pharmacy experience in retail, education and consulting.

My hospital based accomplishments include implementing unit dose distribution systems, pharmacy-based IV admixture programs, establishing a drug utilization review process, performing DUEs, overseeing purchasing and inventory control programs, preparing departmental schedules and a position as acting drug information specialist.

My retail experience includes working in my pharmacist/owner brother-in-law's busy store, which serviced three nursing homes, as well as relief work in Southern Maryland.

I have education experience as a graduate assistant and clinical preceptor for St. John's fourth and fifth year pharmacy students and as a first year clinical preceptor for University of Maryland. My consulting experience includes performing an antibiotic utilization review in a community hospital setting and as an editor for the ACPE program in *Pharmacy Times*. I have also authored a paper that was published in the *New York State Journal of Pharmacy*.

My professional and civic organizational activities include APhA, ASHP, ASPEN, DC Society of Hospital Pharmacists, Southern Maryland Pharmacists Association, Maryland Pharmacists Association, Maryland Hospital Association Speakers Bureau, American Heart Association, Waldorf Lioness Club, and volunteer for Health Partners.

I feel that my distinctive background, as the daughter of a pharmacy dean and former member of the New York State Board of Pharmacy, sister-in-law of a retail pharmacist/owner and my various work experiences provide me with insight and an open frame of mind with which to tackle the business of the Maryland Board of Pharmacy. I will draw on my experiences, as well as those shared family experiences, to best represent all pharmacists of the State of Maryland.

Vote

MORRELL C. DELCHER

105 NORTH BEAUMONT AVENUE
CATONSVILLE, MARYLAND



GRADUATED

1969, UNIVERSITY OF MARYLAND


PRACTICE

Hospital

As a nominee to the Board of Pharmacy, I believe that pharmacists and the profession are at a critical point in defining our role as we move toward the next century.

There are many difficult questions that we must address in immediate terms: the restriction of access to care, reimbursement methodologies, ineffective therapeutic strategies, the selective support of high-cost therapies, the education and empowerment of patients in decisions regarding their health care, and the impact of automation to shift pharmacy practice from distribution to clinical applications.

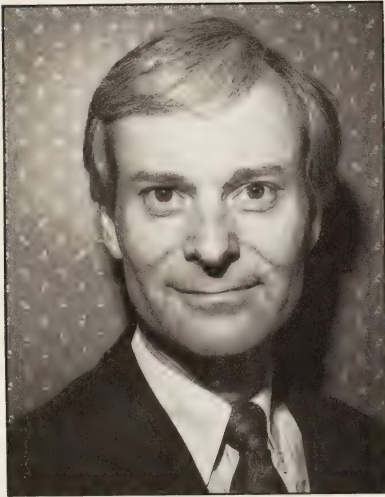
We, the practitioners, now have the opportunity to assume a new role with effective leadership. A leadership that has the wisdom gained from experience and the vision to recognize the need to transform the practice to meet the demands and influences of the future. Although my career focus is hospital practice, it began with a strong influence in a community pharmacy. My experience has been as a staff member of a large academic medical center, with both clinical and administrative assignments; managed health care; medical practice management; and as the Director of Pharmacy at two regional hospitals. After several years of practice, I completed an MBA degree, attended executive programs at Duke University and the Wharton School of Business, and am currently enrolled in a non-traditional Pharm.D. program. My society involvement has been principally with the Maryland Society of Hospital Pharmacists including both elected offices and committee assignments. Participation with national organizations has provided me exposure to issues from other states that could have a potential impact on practices here in Maryland.

If appointed to the Board of Pharmacy I will work to examine the broad picture of health care and the issues that are important to the community of patients and how we as a profession will meet those needs. Pharmacy does not have the freedom to travel these new routes independently. My emphasis is to seek a collaborative vision that has contact with key groups. I consider it a privilege to be nominated to serve on the Board of Pharmacy during this transition in pharmacy practice. 

We are challenged by a rapidly changing healthcare landscape. Emergence of biotechnology, controlled access to healthcare, paperless records, mid-level prescribers, and "re-engineering" are but a few of the many factors that may influence our professional role.

E. ROBERT FEROLI, JR.

802 MORRIS AVENUE
LUTHERVILLE, MARYLAND



GRADUATED
1973, UNIVERSITY OF MARYLAND

PRACTICE
Hospital

Pharmacists are well positioned to meet these challenges. Whether patients are at home, in the hospital, or in long-term care facilities, pharmacists have increasing opportunities to provide direct and indirect care to patients. To be successful in upcoming years, it is important for our leaders to understand the interrelationship between various pharmacy practice settings and between our profession and other healthcare providers.

Now, more than ever, our Board must be proactive in anticipating change and promoting legislation that will protect our patients and will support, not hinder, the ability of pharmacists to practice their profession. During this process, we must focus on abilities of registered pharmacists and not overemphasize degrees or titles.

Our Board must maintain and strengthen links with pharmacy associations and societies and must maintain a membership with representation from many pharmacy practice settings. It is also important to maintain effective communication with other professional boards so that we can deal appropriately with situations where boundaries of practice among the professions become blurred.

My background has provided me with the experience and training that will complement those of the current Board. During my career, I've had the opportunity to work as a community pharmacist in my father's store, a hospital staff pharmacist, and a drug information pharmacist. In my current position as Associate Director of Pharmacy at Johns Hopkins Hospital, my responsibilities include oversight of regulatory matters and performance improvement. While promoting pharmacy services, I regularly practice my negotiating skills through participation on committees attended by pharmacists, nurses, physicians, and others.

My experiences also include helping to develop the initial draft of institutional regulations (which recently has been approved by the Board) and representing Johns Hopkins University as a delegate to three USP Conventions. I currently serve as Secretary for MSHP, Chair for the Maryland State DUR Board, and Assistant Scout Master of Troop 340.

It is an honor to be nominated to serve on our Board and I appreciate your support.

vote

JANET GETZEY HART

5079 Columbia Road
Columbia, Maryland



If appointed to the Board, I will provide the understanding and leadership necessary to move the practice of pharmacy into the Twenty-first Century. Pharmacy, in every aspect, is in an evolutionary process. With the aging of the population, health care reform in the future and the movement of pharmacy services to a payor driven market, the profession of pharmacy must take an active, well organized and well presented approach to our future.

Our Board, now more than ever, must provide the leadership, motivation and professional strategy necessary to move the practice of pharmacy into the new century. I will bring a strong work ethic, a knowledge base strong in management and business and a strong commitment to all aspects of the practice of pharmacy to the Board. While I currently practice in retail chain management, I have practiced in hospital, managed care and consultant services. The Board must develop a strategy to unite all aspects of the profession to move the practice of pharmacy to the forefront of the health care community. I ask for your vote.

Vote

GRADUATED

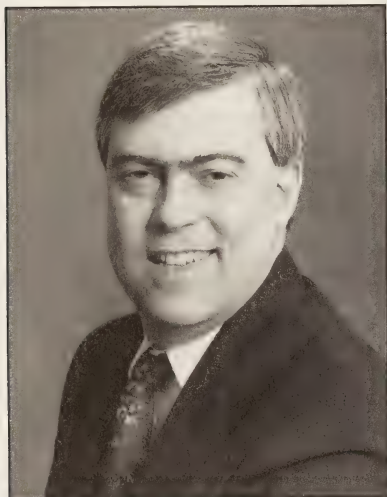
1984, DUQUESNE UNIVERSITY

PRACTICE

COMMUNITY/RETAIL MANAGEMENT

David B. KNAUER

2930 NORTHWIND ROAD
BALTIMORE, MARYLAND



GRADUATED

1971, UNIVERSITY OF MARYLAND

PRACTICE

Hospital

As we move through the health care reform process we realize that communication is necessary to minimize the concerns of payers, providers and recipients of health care. Without communication, fear and uncertainty will originate and, if left to grow, could adversely influence the process of reform. It is therefore critical for us as practitioners to become sensitive to the concerns of our patients and to respond appropriately to ensure their health, safety, and welfare.

By establishing standards of practice which ensure quality care, disciplinary boards serve as conduits for the information process and guardians of patient care. Naturally, members of such groups must possess a broad range of knowledge and skills with a wide array of interests in related activities. I believe that my background closely parallels this criteria.

My professional experience includes many years in the retail, hospital, and educative fields of pharmacy. Retail positions included independent employment positions as well as chain management and executive posts. I am presently a hospital pharmacy administrator with experience gained as a staff pharmacist within the department. I have also served as a past faculty member, Division of Continuing Education, Essex Community College, and currently hold the position of Clinical Instructor for UMAB as a preceptor of pharmacy students.

Professional affiliations include life membership in the Alumni Association, UM School of Pharmacy, as well as a past Board Member, Secretary, Vice President, and President. I have also been a member of the Board of Directors of the Maryland Society of Hospital Pharmacists for the past five years as well as a past Treasurer and member of several committees. I also have the distinction of being the Society's first recipient of the Board of Directors Award, which honors its recipient for significant, consistent, and on-going contributions to MSHP. Furthermore, I am a present member of the American Society of Hospital Pharmacists.

By combining previous experience with new perspectives I believe I can successfully serve the profession and the public as a member of the Board of Pharmacy. My experience and enthusiasm will allow me to become the conduit between the profession and the public to guarantee communication which is critical for the future of health care.

DK

W. IRVING LOTTIER, JR.

4501 WEST FOREST PARK AVENUE
BALTIMORE, MARYLAND



GRADUATED
1959, UNIVERSITY OF MARYLAND

PRACTICE
COMMUNITY/INDEPENDENT

If I am appointed to the Maryland Board of Pharmacy, I promise dedication to my duties governing Pharmacy's laws and regulations. I will be aware at all times that I represent each and every pharmacist in the state, and will strive vigorously to see that the public's interest is served.

Though my experiences for the 35 years of my career have been primarily in the retail pharmacy arena; I have worked as a pharmacist in a hospital and presently I am an official in a HMO/Community health center. These experiences will assist me in the various disciplines.

I recall that my impression of Pharmacy upon graduation was a moderately regulated, lesser appreciated profession with fewer graduates than needed for general attrition. Today Pharmacy is characterized by high technology, well educated "Pharm.D." degree, most respected profession, and far more applicants than the University's can train.

I want to be that board member who protects current pharmacy conditions, monitors events that impact on Pharmacy, while not placing one discipline above another. Finally a successful member must be aware of the ever increasing burdens on pharmacists (example: third party autonomy, HMO influence, mail order, decreasing 3rd party rates.) I hope you will concur my selection to be that person. I believe my experiences as listed will illustrate my skills.

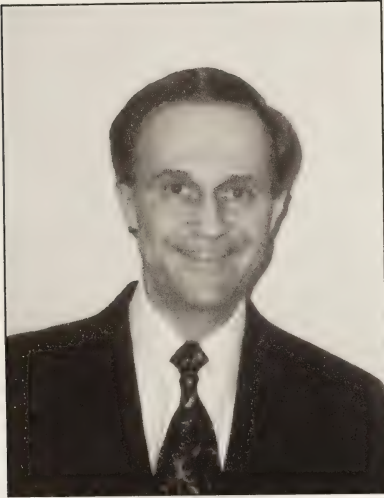
1. Retail Pharmacist/Manager for 33 years.
2. Past President of the University of Maryland School of Pharmacy Alumni Association.
3. Past Chairman of the board Alumni Association.
4. Current chairman of Grant Committee Alumni Association which has been awarded more than \$12,000 for Alumni projects.
5. Member of the Maryland Pharmacists Association.
6. Current member of Legislative Committee MPhA.
7. Current member Maryland Medicaid Advisory Committee.
8. Current member and two time past president of Maryland Pharmaceutical Society.
9. Current board member and treasurer of a 26,000 member HMO/Community Health Center.

Summarily I ask for your vote to achieve another goal of mine, to serve this profession, which has given my wife, children, and myself a comfortable livelihood. This position will hopefully allow me to retire with achievements that impact Pharmacy's future.

Vote

Raymond W. Morris

9805 Millwick Drive
Ellicott City, Maryland



GRADUATED
1972, UNIVERSITY of MARYLAND

PRACTICE
HOSPITAL/MANAGED CARE

I began my career with pharmacy almost 29 years ago working in a small professional store in west Baltimore. What started out as a part-time high school job to pay my way through college, developed into a career. My interest sprang from both the nature of the work itself and the guidance of the individual for whom I worked. Without both influences my choice might not have been as clear to me. To this day, some of the things I like best about being a pharmacist came from my experiences there -- an identification with a respected group of professionals that helps individuals and serves the public.

Clearly, over the years the professional curriculum has changed the way practitioners are trained and the way that they interact within the medical community. One of the things that we can never lose sight of is our own sense of "value" for the services we provide. This transcends the restrictions imposed by the setting in which we practice and is where part of the challenge for our professional future lies. Pharmacists who lead the profession will do so by the wisdom of their actions both at the public and practice levels. Success will be measured by services that offer innovative and effective solutions in what is certainly an unpredictable health care environment.

I graduated from the Pharmacy School in 1972, completed a combined Residency and Master of Science degree program in 1975. In 1983, I received a Master of Business Administration with a concentration in Health Care. I have held management positions in retail pharmacy, institutional, managed care and infusion therapy settings. Currently, I am the Pharmacy Manager at St. Joseph Medical Center in Towson, MD and have worked part-time for the Columbia Medical Plan.

I have always seen myself professionally as a pharmacist, regardless of my practice setting. I realize that what I have gotten from Pharmacy is important to give back both in time and service. I can't think of a better way to express the gratitude I have for the profession and those who have helped me along the way than to serve on the Board of Pharmacy and have a positive impact on the professional lives of all practitioners.

Vote

Jacob R. Raitt

6905 SCOTCH DRIVE
LAUREL, MARYLAND



GRADUATED

1956, Columbia University

PRACTICE

COMMUNITY/INDEPENDENT

I received my first license to practice pharmacy in June of 1957, one year after graduating from pharmacy school and one year into my studies toward my Ph.D.. From that time on, I have done my best to practice pharmacy in a variety of areas, with an eye toward returning this profession to the elevated status which it held in the 1940's and early 1950's when the "corner druggist" was truly "DOC."

I have taught at the college and graduate level: I have taught senior citizens: I have taught the parents of very young children: I have practice in "chain store" pharmacies: I have practiced pharmacy as a hospital staff pharmacist: I have been Director of Hospital Pharmacy operations: I have been Director of Pharmacy for a number of organizations, including a home I.V. infusion company: I have been the Director of a home I.V. infusion company: I have worked free-lance as a "temporary" pharmacist with a great deal of expertise: I have worked for professional independent pharmacies, and I have done both basic and industry oriented pharmacy research. From each of the positions that I have held I have extracted a great deal of knowledge, experience, performance skills and personnel and personal relationships and believe have used them well throughout my career.

It is now time to attempt to focus all of these skills on the advancement of pharmacy into the 21st century. It is time for me to give back to pharmacy the emotional and material sustenance that I have gathered over the years. With the knowledge and maturity that I have gained, I believe that I have the wherewithal to aid in the administration, direction and governing of pharmacy.

Toward these goals, my name has been placed in nomination to serve on the Maryland State Board of Pharmacy. It is one of my ambitions to return to pharmacy more than it has given me, and in doing so, I intend to retain the respect for pharmacy that is tendered toward us throughout the nation, and I intend to nurture and sustain the advancing strides that pharmacy is now making.

Vote



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Hospitals and Health Systems

A Column from the Maryland Society of Hospital Pharmacists

Lori Keys, P.D., MSHP Membership Committee

Recently, MSHP and MPhA have joined forces to work for changing the procedures for Board of Pharmacy nominations. Currently, the Board consists of eight members, six of whom are practicing pharmacists. However, the current law does not require that the six practicing pharmacists represent particular types of pharmacy practice.

MSHP and MPhA both support changing the current law to ensure that there will be, at all times, two pharmacists from independently owned community pharmacies, two from chain pharmacies, one from hospital practice, and one from a recognized pharmaceutical specialty (home infusion, long term care, nuclear pharmacy etc.). Structuring the board to include pharmacists from all practice settings is in the best interest of the State as it ensures that the board will have a global basis from which to make decisions that ultimately affect the public's health.

Pharmacists who receive this issue of *The Maryland Pharmacist* will find a ballot enclosed for the upcoming election for the Maryland State Board of Pharmacy. The election this year is not subject to the proposed legislation described above. The seat that is being vacated has been held by a hospital pharmacist since the 1970's. The MSHP Board of Directors asks that you please vote in this election and that you support the candidates that are currently practicing in hospital settings. You can vote for up to three candidates.

The candidates who are both practicing hospital pharmacists as well as members of MSHP are, in alphabetical order: Mo Delcher, Bob Feroli, Dave Knauer, and Ray Morris.

MSHP hopes that you will agree that it is important to maintain diversity in practice settings among the Board of Pharmacy members and we hope that you will cast your three votes to reflect the need for continued representation from a practicing hospital pharmacist on the Maryland State Board of Pharmacy.



In other news of interest to institutional and hospital pharmacists, the Board of Pharmacy is finalizing regulations affecting your practices. Presently, Maryland has no regulations specific to inpatient practices. This presents problems for the Board, inspectors and pharmacists when they try to apply regulations originally designed for ambulatory practice on the very different realities of hospital and institutional practices. The regulations, worked on by both MPhA and MSHP, are expected to be published in the *Maryland Register* for public comment in the very near future. Copies of the regulations are available from both the MPhA and the MSHP offices.

MSHP conducts regular continuing education meetings for its members. These meetings feature topics of particular interest for institutional pharmacists and we encourage you to attend and see what MSHP is all about. Our March meeting, scheduled to begin at 6:00 pm, March 9 at the St. Joseph's Hospital in Towson, will feature a presentation on pain control.

For more information on our continuing education programs, institutional regulations, or information on how to become involved in MSHP, simply call our offices at (410) 752-3318.

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Maryland Pharmacists

The Entrepreneurs

This Month
Glenn Lichtman, Pharmacist
PharmaSTAT, Baltimore, Maryland

Glenn Lichtman needed a night off. His five year old daughter was in a school play, and he had promised her he would attend. Glenn did not think he would have a problem scheduling another pharmacist. Like most of us, he had a list of relief pharmacists; surely one person on his list would be able to work.

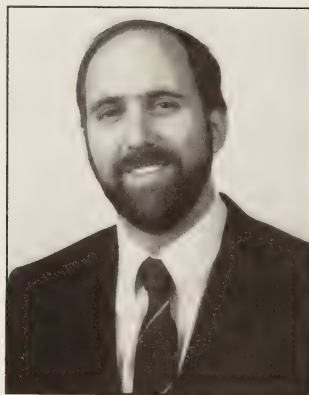
Call after call, pharmacist after pharmacist... nobody was available. He grew more and more frustrated. His wife would understand that he couldn't get to the play (maybe). But how could he tell his daughter? As the night of the performance approached, Glenn realized he was not going to be able to find anyone to work for him.

Glenn was angry as he tried to explain to his young child that he would miss her performance that night. He told his wife, "I wish someone would start a special service just for pharmacists. All you would have to do is make one phone call, the company would ask when you would need a pharmacist, and would match the perfect individual to your situation."

Over the next few weeks, Glenn discussed his idea with other pharmacists. It seemed as though the demand was there, but the service was not. After much thought, he decided to take the plunge. Glenn Lichtman opened a pharmacist employment service. He named his company, *PharmaSTAT*.

Glenn's idea was to specialize. The only personnel provided by his company would be pharmacists and pharmacy technicians. All of his advisors said this was a big mistake. His accountant told him he would never make a profit with a focus that narrow. His lawyer told him that opening a business without a wide base of customers was financial suicide. His consultant told him that even if he did succeed, his company would never grow unless he included nurses, respiratory therapists, bookkeepers, etc.. Glenn listened intently, then made up his own mind. "My field is pharmacy. I know pharmacists and pharmacy technicians. I know the companies that need these people."

After hiring twelve part-time pharmacists and six technicians, Glenn was ready to start marketing his company. Insurance, legal and accounting fees had already consumed his first year's budget. He was now working on money he could not even hope to earn for at least two years. Although his marketing efforts were produced on a shoe string, he refused to lower his standards when it came to the quality of personnel he offered. With a home equity loan, he purchased a custom software package. This program allowed him to match the exact pharmacist or tech to suit his clients needs.



When it was time for the Maryland Pharmacists Annual convention, *PharmaSTAT* was there! Although the display consisted of type written information sheets, hand lettered sign panels, attached to the display curtain with diaper pins, and a bag of Hershey kisses, Glenn was proud to exhibit for his peers.

Reaction to his company was mixed. While most pharmacists agreed that there was a need for this service, some were very candid about their reluctance to use *PharmaSTAT*. One pharmacist, upon seeing the display at the convention, remarked, "I would rather close my store than use a 'Kelly Pharmacist.'" Although somewhat disappointed with the response to his company, Glenn understood some of the reluctance of pharmacy owners and managers who saw themselves as irreplaceable and could not imagine someone else filling in.

Glenn Lichtman was confident that once clients tried his service, they would be pleased with the quality and professionalism of his personnel. Slowly, one client at a time, he had his opportunity. After each job the client was sent a card to rate the person *PharmaSTAT* had sent to their site. The results were impressive. Clients first used personnel for vacations, special projects, and just to take a few days off now and then.

Owners and managers were discovering that *PharmaSTAT* worked - and worked well! In addition, *PharmaSTAT* handled all payroll taxes and made sure each of their personnel were bonded and insured.

In 1990, to solve the problem of a limited client base, Glenn opened an office in Rockville; this allowed his company to efficiently service clients in the Washington DC metropolitan area, including the surrounding suburbs and Northern Virginia. In 1992 an office was opened in Richmond, Virginia to serve Southern Virginia and the Tidewater region of that state. Last year, Glenn expanded again with a new Philadelphia office to service Central and Eastern Pennsylvania.

As *PharmaSTAT* continues to grow, one fact will never change. Glenn Lichtman personally interviews every pharmacist or pharmacy technician he hires for the company. He will not allow anyone else to interview perspective employees, and insists on a face to face meeting with all candidates. Asked why he never accepts applications through the mail, Glenn says "When an interview is conducted in person, I can observe subtleties that would never be noticed on paper or over the phone."

Today, *PharmaSTAT* employs more than 300 pharmacists and pharmacy technicians. *PharmaSTAT* services clients in all practice settings including retail, hospital, institutional and home health care pharmacies. As Glenn says, "When you need a pharmacist, call *PharmaSTAT*!"

MP

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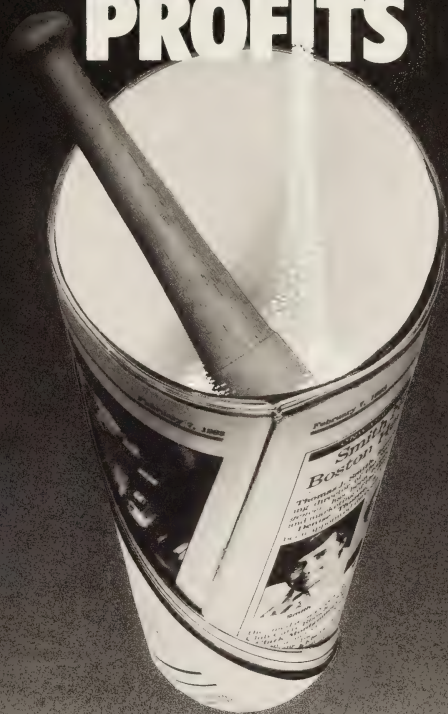
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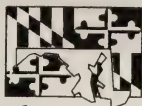
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This lesson reviews the antiepileptic drugs: felbamate (Felbatol) and gabapentin (Neurontin).

Dosage forms and regimens for these drugs are listed in Table 1. At the time of writing this lesson, two other antiepileptic drugs are at various stages of FDA review: lamotrigine (Lamictal) and vigabatrin (Sabrid).

The "1P" noted after the name of the drug signifies that it was given priority approval by FDA because the drug represented a significant advantage over previously available therapy.

There are reportedly 2.5 million Americans affected by epilepsy with 125,000 new cases diagnosed yearly. Epilepsy is not a disease in itself. Rather, it is a symptom of a brain dysfunction with many causes. The orderly discharge of electrical energy in the motor cortex malfunctions. This is usually manifested as a seizure. There are at least 20 different types of seizures, the most familiar are the convulsions involving muscle spasms and unconsciousness. However, these are not the most common type.

A seizure is an abnormal discharge of neurons that causes a change in behavior without the patient realizing what is happening. All patients with epilepsy experience seizures, but not all patients with seizures have epilepsy. The unconscious

contrary to popular belief, most seizures are not convulsions.

Seizure Classification

The two major classifications of seizures are partial and generalized. The origin of partial seizures can be determined and is localized in a specific area of the brain. These almost always result from injury to the cerebral cortex. Partial seizures are further subdivided into simple partial, complex partial and secondary to generalized tonic-clonic seizures.

The origin of generalized seizures is not localized. These involve both hemispheres of the brain simultaneously. They are not due to injury and have no known structural abnormality. Generalized seizures are subdivided into tonic-clonic, absence (typical or atypical), myoclonic and atonic.

Partial Seizures. Partial seizures are the most common type occurring in 65 percent of patients with epilepsy. The older name for this type is "Jacksonian," named after the physician who first recognized that seizures were associated with abnormal electric activity which originated in a particular area of the brain.

With simple-partial seizures, the origin is consistent, there is no loss of consciousness, and there is usually, but not always, muscular activity. The patient can also experience sensory, autonomic and psychic symptoms. These are exhibited as unusual visual or auditory phenomena; vomiting or sweating; or flashbacks in memory or hallucinations. These seizures last approximately 30 seconds.

periods may or may not be accompanied by a loss of control over movements or distortion of the senses. When there is a loss of control of body movements, the focus can be located in only one area or involve the entire body. The seizure can range from a momentary stare into space, to prolonged contractions of muscles over the entire body. The later occurrences are called convulsions, but

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New Drug Review: Antiepileptic Agents

*J. Richard Wuest, R. Ph., Pharm.D.
Professor of Pharmacy Practice, University of Cincinnati*

*Thomas A. Gossel, R. Ph., Ph.D., Interim Dean
Ohio Northern University*

A professional development program made possible by
an educational grant from **SEARLE**.

Complex-partial Seizures.

These have a consistent point of origin in the brain. The patient experiences impaired consciousness, is often confused, and has a blank stare. These last one to two minutes. After the seizures, patients experience amnesia and confusion as to their whereabouts. Complex-partial seizures are the most common type that occur in adults. They are also the most difficult to control.

Both simple-partial and complex-partial seizures can progress to (secondary) generalized seizures. It has been reported that most adults who say they have "Grand Mal" epilepsy actually have generalized-partial seizures.

Generalized Seizures. Although generalized seizures are more familiar to most people, they are not the most common type of seizure. As stated above, this type may actually have a localized origin and, therefore, advance from partial seizures.

Generalized tonic-clonic seizures were once called Grand Mal epilepsy. Attacks begin with the body becoming rigid (tonic). The patient may fall to the ground. The episode lasts about a minute or less. This is followed by muscle jerks (clonic), shallow breathing, loss of bladder control and excessive salivation (foaming at mouth). The jerking and muscle movements are bilateral, continuing for a few minutes and then stopping. After the attack, the patient is drowsy and confused for moments or hours.

The older name for generalized absence seizures is Petit Mal epilepsy. The condition is further subdivided into typical and atypical, to be explained shortly. With either type, there is an interruption in the patient's ongoing activities accompanied by a blank stare and rotating eyes. Attacks are of short duration, only a few seconds, and they can occur many times (paroxysmal) each day.

There may also be uncontrolled movements (automatisms) such as facial movements, chewing, rapid eye blinking, or arm or leg twitches or jerks, but no overt generalized convulsions as seen with tonic-clonic seizures. Children with absence seizures have problems in school because they are perceived to be daydreaming when they are actually having a seizure. This interferes with learning because they have no recollections of what is taught during the seizure. Sadly, about 50 percent of children with absence seizures develop generalized tonic-clonic seizure activity when they grow older.

Typical absence seizures have a sudden onset and seizures begin when the patient is a child. They occur intermittently and usually stop when the individual reaches adulthood. Atypical absence seizures have a gradual onset and cessation. They often continue into adulthood and coexist with other types of seizures.

Myoclonic generalized seizures are sudden, massive and brief muscle jerks that can involve the entire body. Muscle movement can be so violent that the patient is thrown to the ground. Alternately, they can be sudden, nonmassive and quick jerks of the arm, leg, hand or foot. Consciousness is not lost during the attacks, but they can occur during sleep.

Atonic generalized seizures are characterized by a sudden loss of both muscle tone and consciousness. The patient may collapse, the head may drop and jaw slacken. An arm or leg may go limp. Seizures last a few seconds to a minute, but then the patient can stand and walk again. Both myoclonic and atonic seizures can occur in patients with other types of epilepsy.

Lennox-Gastaut syndrome and status epilepticus are two other types of seizures that should be mentioned. Lennox-Gastaut syndrome, for which felbamate is indicated, is a condition that occurs mainly in preschool-age children. Seizures are multiple and hard to control. The seizure types are myriad including atonic, myotonic, atypical-absence and generalized tonic-clonic spells. The child invariably has some degree of psychomotor retardation and neurologic impairment. Between 3 and 10 percent of children with epilepsy have Lennox-Gastaut syndrome.

Status epilepticus is not really a seizure type. Instead it is a situation where seizures occur in rapid succession, and the patient loses consciousness during and between the seizures. The milder forms involve complex partial, absence and atypical absence seizures which can last for hours.

New Antiepileptic Agents

| Generic | Brand | Availability | Dosage Regimen |
|------------|-----------|--------------------------------|---|
| felbamate | Felbatol | 400 & 600 mg 600mg/5ml susp | 1200 mg daily in 3 to 4 divided doses |
| gabapentin | Neurontin | 100, 300, 400mg capsules | 900 to 1800 mg daily in 3 divided doses |

Table 1

With the more serious type, convulsive status epilepticus, the continuous tonic-clonic convulsions, high fever, and lack of oxygen in the blood can be severe enough to cause brain damage or even death. It is estimated that as many as 10 percent of patients who develop convulsive status epilepticus die regardless of treatment.

What Causes Epilepsy?

Epilepsy appears to occur due to simultaneous firing of groups of neurons, often with no overt exogenous trigger. When the neurons fire, there is an imbalance between the excitatory and inhibitory neurons and the neurotransmitters that innervate them. Glutamate is the major excitatory neurotransmitter in the CNS. Gamma-aminobutyric acid (GABA) is the inhibitory neurotransmitter. As will be seen later, glycine and aspartate are also involved. The biogenic amines: norepinephrine, dopamine, serotonin, and acetylcholine, and steroids also modulate the thought processes and motor activity, but GABA and glutamate play the greatest role in CNS.

In the brain, for proper thought processes and motor control, each neuron forms thousands of excitatory and inhibitory synapses

with other neurons. The balance between the number of excitatory and inhibitory inputs along these neurons and synapses determines whether a given neuron fires. When discussing epilepsy, the two major neurotransmitters to consider are glutamate and GABA.

Glutamate and GABA have a common metabolic pathway. Thus, the rate at which they are formed depends on the level of enzymes present. In healthy persons, there is a balance between excitation and inhibition. Disturbing the enzyme systems will disrupt this balance and lead to seizures, especially when there is a high glutamate to GABA ratio.

Seizures are thought to occur when there is a shift in glutamate levels without a corresponding increase in GABA. Some types of seizures are thought to be caused by a shortage of the inhibitory neurotransmitter GABA and/or the enzyme (glutamic acid decarboxylase) that is responsible for its synthesis. Other types of seizures are thought to occur because of increased levels of glutamate. This can occur when there is an increased rate of synthesis of glutamate from its precursor, glutamic acid.

Antiepileptic Drugs

Several effective drugs have long been used in the treatment of epilepsy beginning with phenobarbital in 1917, followed by phenytoin (as diphenylhydantoin) in 1938, carbamazepine and valproate in the 1970's. Several other drugs have been used less frequently along the way. Although interest in new antiepileptic drugs has been low over the past 15 years, four new drugs have been, or will soon be, approved for therapy within months of each other.

The need for additional drugs is critical because 30 percent of patients with epilepsy are poorly controlled with medication, and another 30 percent do not comply with therapy because of the side effects caused by the drugs. The most bothersome adverse effects are sedation and loss of cognitive ability. The mechanisms of action of the new antiepileptic drugs are different from previously available agents. A brief review of how the older drugs work is in order, since the newer ones will often be used in combination with them due to their synergistic action.

Regardless of the exact mechanism of action of antiepileptic drugs, they all affect neuronal excitability by altering membrane permeability to one or more ions. Carbamazepine and phenytoin block sodium, and possibly calcium, transport across neuronal membranes. This stabilizes the membrane and renders the neuron less likely to fire.

Phenobarbital and benzodiazepines reduce neuronal firing by increasing chloride entry via an indirect action on the GABA receptors. Valproate increases chloride entry also, by increasing GABA levels in the brain. Ethosuximide reduces calcium transport into neurons.

The basic principle of neuronal activity and firing is that neurons exist in three stages; depolarized (resting), polarized (firing) and repolarized (returning to the resting state). Polarization and firing occur because sodium and calcium enter the neuron. When sufficient amounts of these ions enter, an electrical charge is transmitted along the cell to its end points (bulbs), where chemicals (neurotransmitters) are released. These chemicals pass the impulse to other neurons in the area. When this happens excessively, neurons fire uncontrollably and a seizure occurs.



herefore, lowering the entry of sodium or calcium, or increasing the cellular content of chloride,

maintains the neuron in its resting state and prevents excessive firing. This has been the basis of drug therapy for epilepsy in the past.

The newer drugs are aimed more at altering glutamate and GABA rather than directly affecting ion entry into neurons. They will often be used initially in combination with previously available drugs for several reasons.

1. Approximately one-third of patients currently receiving antiepileptic drugs do not get adequate control of their seizures.
2. The newer drugs appear to cause fewer side effects. Their use may allow a lower dose of an older drug, thus reducing its adverse effects.
3. A third and very important reason is the ethical consideration inherent in switching the patient to new drug (like an antiepileptic) as sole therapy and depriving them of a drug known to be effective.
4. Persons with severe epilepsy are most likely to need combination therapy.

Felbamate (1P)

Trade Name: Felbatol

As the name implies, felbamate is a derivative of meprobamate. However, it has no antianxiety or muscle relaxant activity. It blocks sustained, repetitive neuronal firing by increasing seizure threshold and decreasing the spread of seizures. Two of the chemicals involved in initiating/reducing and propagating/preventing seizures are glycine and aspartate.

In this instance, glycine is important because it stimulates a part of the physiologically active receptor sites on neurons. These are called the NMDA (N-methyl-D-aspartate) receptors. Glycine binds to and stimulates the NMDA receptors. This opens the calcium channels of the neurons' membranes. Calcium enters and activates the neurons. When this occurs excessively, it initiates and propagates seizures.

Felbamate appears to inhibit the ability of glycine to attach to its binding site on the NMDA receptor.

It was anticipated that felbamate would make a significant impact in seizure therapy. This did occur in that over 100,000 patients were being treated with it within six months of its release. Its acceptance in therapy was based on its action

Felbamate was approved for partial seizures in adults with or without secondary generalized seizures. It was also indicated for treating children with Lennox-Gastaut syndrome, the most severe form of childhood epilepsy. Many consider it to be the agent of choice for this condition.

should be suspended, unless in your judgement, the patient's well-being is judged to be so dependent upon continued treatment with Felbatol that abrupt withdrawal is deemed to pose an even greater risk."

The letter further noted that "...the absolute rate (of aplastic anemia) may be higher than the nine in 50,000 patient years of exposure (Editors note: 100,000 patients taking a drug for six months equals 50,000 patient years) because every case of drug-induced aplastic anemia is typically delayed in onset by weeks to months after initiation of treatment and post-marketing surveillance captures only a fraction of incident cases."

This is an excellent example of the importance of physicians and pharmacists participating in FDA's MedWatch adverse drug reaction and USP Practitioners' Reporting Network programs. Most of the nine cases of aplastic anemia were reported via MedWatch, and were not seen in the manufacturer's post-marketing surveillance program.

This is not an unusual situation. Overwhelmingly, drug-induced adverse reactions are discovered, not by looking for them, but by practitioners in different parts of the country sending in anecdotal reports eventually leading to a trend. The same is the case for defective product reports. Involvement in these programs can improve patient care and save lives. Apathy toward them can be disastrous. Information on these programs can be obtained from the sources listed in Table 2.

Reporting Systems for Adverse Drug Reactions and Defective Products

FDA MedWatch (800) FDA-1088
5600 Fishers Lane, Rockville, MD 20852-9787
Fax (800) FDA 0178
Modem (800) FDA-7737

USP Practitioners' Reporting (800) 4-USP-PRN
12601 Twinbrook Parkway, Rockville, MD 20852

Table 2

being different from older antiepileptics. Therefore, it provided the option of using the drug in combination with other to maintain patient control and reduce side effect potential, or using it in patients who did not respond to previously available antiepileptic agents.

Felbamate was considered to be an improvement over older therapies in terms of both efficacy and side effects. In clinical trials it reduced the number of seizures in epileptic adults from 21 to 12 per month when compared to valproate. In adjunctive therapy with phenytoin or carbamazepine, it reduced seizures by 23 percent.

Unfortunately, after its release, felbamate was linked to an inordinate number of cases of aplastic anemia. This is a rare but fatal blood dyscrasia resulting from bone marrow failure. Since it affects less than five persons per million, aplastic anemia was not seen in clinical trials (approximately 1,000 patients). However, after felbamate became available for general use, nine cases of aplastic anemia were reported in 100,000-plus patients taking it. Two of these patients died.

FDA estimated this to be 50 times higher than what should be expected in this size patient population. After consultation with FDA, the manufacturer of Felbatol sent a "Dear Doctor" letter to physicians informing them that "...the use of Felbatol

At the time of writing this lesson, there was no absolute proof that felbamate was the cause of the aplastic anemia. At this point, FDA apparently has three options under consideration:

1. remove Felbatol from the market;
2. limit its use to a specific population; or,
3. determine whether aplastic anemia is or is not caused by felbamate mono-therapy (since it is most often used concurrently with other drugs which may, alone or in combination with felbamate, be the cause).

Currently, Felbatol remains on the market, but its prescribing information has been revised to carry the "boxed warning":

"...Felbatol should only be used in patients whose epilepsy is so severe that the risk of aplastic anemia is deemed acceptable in light of the benefits conferred by its use."

Gabapentin (1P) - Trade Name: Neurontin

Gabapentin is related to GABA structurally. It was synthesized originally with the intention that it would be a GABA agonist. However, it was soon found that gabapentin does not bind to or stimulate GABA receptors. It is not converted to GABA in the body nor does it inhibit GABA uptake or metabolism. Instead, its mechanism of action appears to be related to binding with its own specific receptor site on neurons and thereby enhancing GABA activity.

Gabapentin is officially indicated for adjunctive therapy in the treatment of partial seizures with or without secondary generalization in adults with epilepsy. The drug is neither an enzyme inducer nor inhibitor, so it has not been linked to the interactions caused by other antiepileptics. However, magnesium and aluminum antacids may reduce its bioavailability by about 20 percent when administered concurrently. Its manufacturer recommends that Neurontin be taken at least two hours either side of a dose of antacid.

Determining the specific side effect profile for gabapentin is difficult because it is not indicated for use as sole therapy. However, side effects reported by the manufacturer at the 5 percent or higher level are: somnolence (19.3 percent versus 6.9 percent for the placebo); dizziness (17.1 vs 6.9 percent); ataxia (12.5 vs 5.6 percent); fatigue (11 vs 5 percent); nystagmus (8.3 vs 4 percent); tremor (6.8 vs 3.2 percent); and double vision (5.9 vs 1.9 percent).

The usual adult dose of Neurontin is 900 to 1800 mg per day given in three divided doses. Its absorption is not appreciably affected when it is given with or without food. Additional information useful in counseling patients is listed in Table 3.

MP

Patient Information for Neurontin

Neurontin is used to control convulsions, seizures and other conditions as determined by your doctor.

Take Neurontin with a full glass of water. If it upsets your stomach, you may take it with food.

Do not change the amount of medication taken or stop taking it without consulting your doctor.

Some people may experience dizziness, blurred vision or drowsiness from Neurontin. If you do, be careful driving or performing hazardous tasks. Alcoholic beverages can increase the drowsiness effects.

If you are taking the antacid Maalox, the manufacturer recommends taking Neurontin at least 2 hours after the Maalox dose.

If you miss a dose of Neurontin, take it as soon as possible. But, if it is almost time for your next dose, skip the missed dose and go back to your regular dosage schedule. Do not take a double dose, unless directed by your doctor.

In case of accidental ingestion or overdose, call your doctor or poison control center immediately.

Women: While taking Neurontin, you should tell your doctor if you become pregnant or plan to become pregnant or if you are breast-feeding an infant.

Most patients experience few or no problems while taking Neurontin. However, be sure to tell your doctor if the following occur: nausea, vomiting, unusual tiredness, increased appetite, nervousness, uncontrolled eye movements, or any other unusual, bothersome effects.

Adapted from the Pharmex Pals (patient advisory leaflets). For more information, call (800) 233-0585.

Table 3

Continuing Education Quiz

March 1995 -- Antiepileptics

This month's questions are taken from the article on recently introduced drug therapies for antiepileptic that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. There is **no charge** for this quiz for MPhA members (non-members \$5.00). The completed quiz for this issue must be received by August 31, 1995. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name _____

Address _____

City/State/ZIP Code _____

1. In relation to epilepsy, the major excitatory neurotransmitter in the brain is:
 - a. gamma-aminobutyric acid
 - b. norepinephrine
 - c. glutamate
 - d. serotonin
2. All of the following are true *except*:
 - a. epilepsy results from a malfunction of the orderly discharge of electrical energy in the motor cortex.
 - b. a seizure is an abnormal discharge of neurons that causes a change in behavior without the patient realizing what is happening.
 - c. all patients with epilepsy experience seizures, but not all patients with seizures have epilepsy.
 - d. the most common type of epilepsy is convulsive involuntary muscle spasms and unconsciousness.
3. The origin of which of the following types of seizures can be determined, and is localized in a specific area of the brain?
 - a. Absence
 - b. Myoclonic
 - c. Atonic
 - d. Partial
4. Which of the following statements about gabapentin is true?
 - a. It inhibits GABA uptake and metabolism.
 - b. It inhibits the monoamine oxidase enzyme system.
 - c. It should be taken at least 2 hours either side of a dose of an antacid.
 - d. It binds with and stimulates GABA receptors.
5. The older term for generalized-absence seizures is:
 - a. Grand Mal
 - b. Jacksonian seizures
 - c. Lennox-Gastaut syndrome
 - d. Petit Mal
6. After felbamate was released to the market, a boxed warning was added to its package insert concerning the potential for:
 - a. aplastic anemia
 - b. cardiac arrhythmias
 - c. CNS depression
 - d. seizures
7. A basic principle of neuronal activity is that neurons are resting when they are:
 - a. depolarized.
 - b. polarized.
 - c. repolarized.
 - d. up-regulated.
8. In relation to epilepsy, the major inhibitory neurotransmitter in the brain is:
 - a. gamma-aminobutyric acid
 - b. norepinephrine
 - c. glutamate
 - d. serotonin
9. Simple-partial seizures are characterized by all of the following *except*:
 - a. flashbacks in memory.
 - b. loss of consciousness.
 - c. unusual visual or auditory phenomena.
 - d. vomiting and sweating.

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Rx LICENSE TAGS are still available! A special benefit "for members only" that costs only a nominal fee. If interested, call Mary Ann at the MPhA offices toll-free, (800) 833-7587.

Placing an Ad

Have something to sell, rent, or trade? Need a pharmacist? Looking for a new position? MPhA members can place a classified ad in *The Maryland Pharmacist* for free. MPhA will remove member ads after six months unless otherwise notified by the member. Non-members may also place a classified ad. The ad placement charge is \$10 for a maximum of 50 words plus 50 cents per word greater than 50. To place an ad, call MPhA at (800) 833-7587.

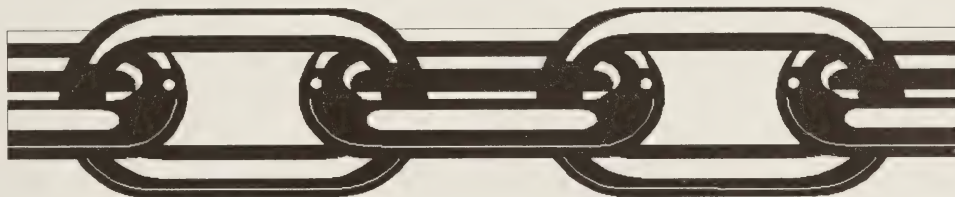
Next Month's Issue!

The 1995 Salary and Benefits Survey



Miscellaneous

WANTED Baltimore pharmacy artifacts and objects (especially local pharmaceuticals, advertising posters and counter top displays) for Baltimore Museum of Industry. Call (410) 727-4808, extension 4.



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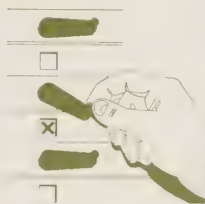
Baltimore, Maryland 21201

(410) 727-0746

Did You Vote Yet?

The March issue of *The Maryland Pharmacist* is all about the 1995 Board of Pharmacy elections. Inside are statements from the eight candidates. The issue, accompanied by a ballot and return envelope, was mailed to all Maryland pharmacists in late February.

All ballots are to be returned to the MPhA offices by April 1. Don't forget that you can vote for one, two or three of the nominees. The three nominees who receive the most votes will be the names submitted to Governor Glendenning for appointment.



Welcome New Members

The following pharmacists recently joined the MPhA and were approved by the Board of Trustees at its March 9 meeting:

- Karen Cranford
- Pamela Wooten
- Vincent Regimenti
- Marion R. Chodnicki
- Jean Dinwiddie
- Irvin Kamantz
- Barry Roberts
- Gary Flax

March 1995

The MPhA Newsletter is published monthly except during the months of July and August when the issues are combined. For information about any article contained herein, contact MPhA at (410) 727-0746 or toll-free at (800) 833-7587. President: Arnold Davidov, P.D.; Chairman, Board of Trustees: Howard Schiff, P.D.; Production Manager: David Miller, P.D..

Court Appeal Goes Against Pharmacy

The Maryland Court of Appeals has handed down its decision in *Weiner, et. al. v. Maryland Insurance Commissioner*. Unfortunately, the ruling was not in pharmacy's favor.

As reported in previous issues of this newsletter, four pharmacists sued the Maryland Insurance Commissioner in January of 1994. Their case alleged that the Commissioner had failed to provide them with an adequate due process hearing in a case involving a reduction in reimbursement from Blue Cross and Blue Shield of Maryland. After losing the case in the Circuit Court, the pharmacists appealed to the Maryland Court of Special Appeals. Jurisdiction over the appeal was exerted by the Court of Appeals, Maryland's highest court. Arguments were heard before this Court in November.

In their recent decision, the Court of Appeals unanimously denied the pharmacists claim because "a party is entitled to a quasi-judicial hearing before an administrative agency only if that type of hearing is required by statute or regulation or mandated by constitutional due process concerns." The Court concluded that the absence of a specific, explicit provision for a hearing meant that the



legislature did not intend that a hearing was necessary. The Court further concluded that, according to the law, the only party actually entitled to a hearing before the Insurance Commissioner are insurers, not consumers, not providers, and not policy holders.

"The Court's decision was extraordinary," says the pharmacists' attorney **Joseph Kaufman**. "Their ruling essentially says that the only people entitled to a hearing on issues related to insurance are the insurers themselves. Where is the consumer protection in this instance? Where in this scenario is the basic right of a provider to have their concerns?"

Clearly, to preserve any provider's right to a contested case hearing in the future, the legislature must be encouraged to pass legislation mandating that right. MPhA will make this issue a priority for our future legislative agenda.

Crammed In Like Sardines

Well, maybe it wasn't *that* tight. Almost 300 pharmacists turned out on Sunday, February 26 for the 1995 MPhA Mid-Year Educational Meeting.

The program featured two excellent seminars and three exceptional speakers. The morning program on Pharmacists Liability was given by Gerald Mazzucca, a pharmacist/attorney who is the current Executive Director of the Philadelphia Association of Retail Druggists. His presentation was sponsored by Boots Laboratories. Our second program was presented by Drs. "Buzz" Kerr and David Roffman of the University of Maryland School of Pharmacy. They did a three-plus hour review of new drugs introduced in 1994.

Of especial value and importance to MPhA? Almost 20 percent of the attendees were *non-members!* Each of these non-members were personally invited to join the Association and we hope to see them back next year.

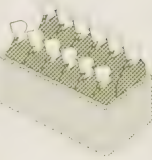
New Member Benefit

In its ongoing effort to make membership in MPhA irresistible, the Board of Trustees has ordered two two-hour continuing education booklets from the Institute for Contemporary Pharmacy Research. These booklets will be mailed along with upcoming issues of the journal to members only. Adding these four free credits to the 12 free credits in the monthly journal means that MPhA members can meeting their continuing education requirements each year at no added cost.

Surf with Mr. Yuk

You won't see his little green face catching a wave at Acapulco or Cancun, but you can right here in Maryland. In a unique educational experiment, the Maryland Poison Center has gone on-line to spread its poison prevention message. People with computer access to the Internet can reach Mr. Yuk by contacting their World Wide Web site at (<http://www.pharmacy.ab.umd.edu>). From there, general information about unintentional poisonings -- including a checklist of common household products that can be harmful if used improperly, a listing of poisonous plants, snakes and spiders -- is just a click away.

The Internet access is a consumer service and *should not* be used for reporting a poisoning emergency. That number remains (800) 492-2414 or (410) 528-7701.



Pharmacy Loss

Karl-Heinz Rösler, former Associate Professor in the Pharmaceutical Sciences at the University of Maryland School of Pharmacy, died on Friday, March 3, 1995 after a long illness. Many Maryland graduates remember Dr. Rösler's lectures in pharmacognosy, medicinal chemistry and herbalism. A resident of Catonsville, he is survived by his two sons, Michael and Markus, his mother and one sister.

Long-time Medical Assistance pharmacist **George Lichter** died unexpectedly on Monday, March 6, 1995. Anyone who ever had to get a pre-authorization or straighten out a billing problem at Medicaid has talked with George. He was a regular "institution" at Medicaid/Pharmacy Liaison Committee meetings and a special help to the staff of Mid-Atlantic DUR and the Maryland Pharmacists Association. He is survived by his wife, two sons and numerous grandchildren.

P&G Links OTCs

Ever been frustrated that patients may visit your pharmacy for prescription services but go elsewhere to shop for their OTC needs? How can you effectively counsel a patient about their medication uses when you only have part of their drug taking history? A new Procter and Gamble program is designed to encourage patients to buy their OTC medicines where they purchase their prescriptions.

A \$5.00 consumer mail-in coupon for P&G products is appearing in newspaper supplements this month. The coupon requires proofs-of purchase of a prescription and two P&G products on the same cash register receipt. The coupons are valid from March 5, 1995 through May 31, 1995. Note

that the coupons must be mailed in by the consumer to receive the \$5.00 rebate.

Hey, Pardner....

Brush off your boots and strap on your spurs. The time is drawing near for the 113th Annual MPhA Convention. A New Frontier for Pharmacy will be held at the Sheraton Ocean City Hotel June 18-21, 1995. Registration and program materials will be mailed to all members in mid-April and will also appear in the May issue of *The Maryland Pharmacist*.



Thank You!
The financial support of the
following companies
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Call for Resolutions

Ever wondered where or how MPhA comes up with the positions it puts forth to the public, the legislature, and the media? That's easy, they come from you!

Each year at the Annual Convention, the MPhA House of Delegates considers a series of member submitted resolutions. These resolutions

-- focusing on an issue or topic of concern to a member or several members -- are then debated during the

House of Delegates Second Business Session. If adopted, those resolutions become formal policy for the organization.

The involvement of members in developing policy is an integral and essential part of our organization.

Mark Sanford, chairman of the MPhA House Resolutions Committee invites all members to submit a resolution. If you're interested, the resolution should be presented *in writing* to the Committee before April 15, 1995. Resolutions have also been requested from all recognized and affiliated organizations.

Can They? Not Usually!

The MPhA office serves as a quick and easy source of information. Perhaps one of the most frequently asked questions is: "Can a nurse practitioner write for a controlled substance?" This question was answered some time ago in *The Maryland Pharmacist* but it does bear repeating.

Only an authorized prescriber with a DEA permit may write a prescription for a controlled substance. Unless a nurse practitioner has his or her own DEA number, they cannot write for a scheduled drug. If a nurse practitioner wants a particular patient

to have a controlled substance, a prescription must be issued by the authorized prescriber with whom he or she has a contractual relationship.

There is an initiative in Washington that would provide mid-level practitioners (nurse practitioners, physicians assistants, nurse midwives) with DEA numbers.

However, until that happens, pharmacists may only dispense a controlled substance on prescription from a prescriber with their own DEA number.



Can They? Part II

The other question we often hear is whether or not prescribers are permitted to dispense from their offices. Several years ago, MPhA was successful in having a comprehensive law governing prescriber dispensing. In summary, a physician, dentist, nurse practitioner may dispense from their offices provided that: 1) they have been issued a permit to dispense from their own professional Board, 2) they comply with all labeling and record keeping laws required of pharmacists and pharmacies, and 3) each patient issued a prescription must be given the choice of taking that prescription elsewhere to be dispensed.

If you have concerns about a particular dispenser, please provide the MPhA offices with their name and complete office address. We will then request a formal inspection from the Division of Drug Control. Please note that it is our policy **not** to reveal the name of the pharmacist or pharmacy who brought this issue to our attention unless specifically authorized to do so by the complainant.

Upcoming Health Events

Telephone numbers are provided for additional information and promotional materials.

April

Alcohol Awareness Month (212) 206-6770
National Anxiety Month (201) 763-6392
Stress Awareness Month (410) 732-1900
Organ & Tissue Donor Week (23-29) . (800) 622-9010

May

Better Hearing Month (202) 628-3507
Better Sleep Month (202) 452-9428
Arthritis Month (404) 872-7100
Asthma and Allergy Month (202) 466-7643
Hypertension Month (301) 251-1222
Mental Health Month (800) 969-6642
Nursing Home Week (14-20) (202) 842-4444
Osteoporosis Week (14-20) (202) 223-2226

DUR Reviewers Needed

Mid-Atlantic DUR is seeking interested, committed pharmacists to do face-to-face educational interventions with physicians and pharmacists throughout the state. This "counter detailing" is designed to bring therapeutic problems to the attention of prescribers through professional, one-on-one meetings.

Reviewers must:

- Have a thorough working knowledge of current therapeutics.
- Keep up-to-date on current practice standards by virtue of continuing education or other means.

If interested, contact DUR Services Director Richard Baylis or DUR Assistant Donna Clatchey at (410) 727-6122.

Maryland Pharmacy Event Calendar

- April 1 UMAB/Rx Open House for Prospective Pharmacy Students, (410) 7076-0756 to register.
 April 9 AZO CE Program, 9:30 am, Pikesville Holiday Inn. Call David Banks at (410) 655-0977.

April 20 MPhA Board of Trustees Meeting, MPhA Headquarters, 7:00 pm.

- April 23 CE Program "New Drugs", VA Medical Center/Perry Point, 8:00 am, Call (410) 642-2411, ext 5466.
 April 24-9 NARD Fitting School Exam (Camp), Milwaukee, WI. Call NARD at (800) 544-7447.
 April 25 UMAB/Rx Alumni Association Meeting, 8:15 pm, Room 740, School of Pharmacy.
 April 26 Eastern Shore CE Program, "Tuberculosis," Rustic Inn, Easton. 8:00-10:00 pm.
 May 8-12 NARD Fitting School/Exam (OTC), Dallas, TX. Call NARD at (800) 544-7447.
 May 8-9 NCPIE 10th Conference on Prescription Medicine Information, Washington, DC. (202) 347-6711
May 18 MPhA Board of Trustees Meeting, MPhA Headquarters, 7:00 pm.
 May 21 AZO CE Program, 9:30 am, Pikesville Holiday Inn. Call David Banks at (410) 655-0977
 May 23 Washington County CE Program, American Legion, 7:00 pm. Call Chris Brown at (301)
 June 4 Washington County Golf Outing and CE. Call Chris Brown at (301)
June 18-21 MPhA Annual Convention, A New Frontier for Pharmacy, Ocean City
 July 13-16 AmeriSource "Celebrate the Music" 9th Annual Trade Show, Opryland Hotel, Nashville, TN
 Oct 28 BMDA Annual Dinner Dance and Awards Banquet, Sheraton Towson

Get Revenge!

Remember the butterflies in your stomach on the day you sat for the Board exam. Now you can help instill that tradition in new pharmacists.

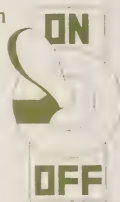
The National Association of Boards of Pharmacy (NABP) is seeking volunteers to serve the profession by writing questions for the national licensing examinations. NABP is looking for a broad range of geographic, demographic, education and practice perspectives. Although question writers do not typically call their work easy, they do consider it rewarding.

To volunteer, contact NABP Associate Executive Director Mary Jo Hunst at (708) 698-6227.

Fax Off!

Within the past few weeks, MPhA has been sending out FAX Alerts on a variety of issues. Unfortunately, we're not reaching everybody we'd like.

Please make sure that the MPhA offices has your pharmacy's FAX number on file and in our Pharmacy Alert System. All you need to do is FAX us a quick note with your pharmacy name and FAX number (don't forget your area code).



NEWSLETTER

The Maryland Pharmacists Association

650 Lombard Street
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MARYLAND PHARMACIST

April, 1995

Vol. 71, No. 4

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Survey

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MARYLAND PHARMACIST

The Official Publication of The Maryland Pharmacists Association

April 1995

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MPHA President Arnold Davidov ponders the latest horror story about pharmacy -- and it isn't what you might think.

5 The 1995 Survey of Pharmacists' Salaries

The results of our January survey show that salaries are up. And so is the number of pharmacists looking for greener pastures.

10 Litigation Update

Columnist David Brushwood reviews a case where the responsibility of a pharmacist to counsel everybody is at issue.

14 Supporting the Profession

A new feature for our journal profiling the pharmaceutical industry. Schering Laboratories talks about their programs to help pharmacists.

16 At Issue

The first in a series of articles written by first-year pharmacy students. This month Chris Buchar looks critically at the relationship between professionals and their financial interests.

18 We Get Complaints

Ever wonder how the Board of Pharmacy fields consumer complaints? Commissioners Mel Rubin and Ted Litwin take you on a guided tour.

21 Interactions

Dean David Knapp talks about the need to nurture professionalism in our future colleagues.

24 Continuing Education

This month we present Part VI in our ongoing update of new drugs and drug therapies. Featured are antidepressant agents. Don't forget to complete the CE quiz on page 30 for credit! It's *free* for all MPA members.

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Articles and editorials that appear do not necessarily reflect the official positions of the Maryland Pharmacists Association and may contain views and opinions for which the authors hold sole responsibility.

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Whenever the opportunity arises, please thank them for their support.

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President's Commentary

A Horror Story for Every Employee Pharmacist

A Rite Aid pharmacist plays a pivotal role in horror-writer Stephen King's latest novel, *Insomnia*. The pharmacist, Joe Wyzer, encounters the novel's main character, Ralph Roberts, when he comes into the pharmacy to buy something for his sleeplessness. After talking with Roberts for several minutes about the pros and cons of over-the-counter sleep aids, Wyzer suggests that he take his break so that they can sit down to chat about insomnia.

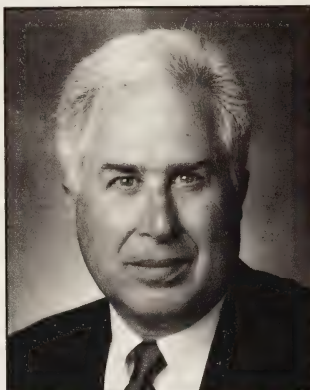
They walk down the block to share a piece of pie and some coffee in the local diner. After giving Roberts an overview of the causes of insomnia -- including an impressive review of REM sleep and the importance of dreams -- pharmacist Wyzer recommends a follow-up with two local specialists. Wyzer then gives Roberts the phone numbers of the specialists, calls one to schedule an appointment for Roberts, and then provides his own home phone number. Before Roberts leaves the pharmacy, Wyzer tells him to keep in touch and let him know what happens. (In true Stephen King style, what does happen next to Roberts is something a little more serious than an inability to get enough sleep. You'll have to read the novel to find out.)

Two things struck me about this fictional pharmacist/patient encounter. King, a non-pharmacist, has perfectly captured the concept of pharmaceutical care on just a few short pages. His Joe Wyzer character is portrayed as a likeable and knowledgeable health practitioner who really cares about his patient's needs -- both spoken and unspoken. He spends time with the patient to hear about and discuss symptoms. He counsels the patients about sleep aids. He recommends treatment. He plans to follow-up with the patient about the treatment and the condition. In other words, he does everything that is embodied within the pharmaceutical care model we've all been hearing about. I wonder how many *Insomnia* readers wish they had a pharmacist like Joe Wyzer?

But, you know what really caught my eye about this exchange? The pharmacist *took a break from filling prescriptions!* And, he did it without pause to worry whether 10 or 20 prescriptions were stacked up waiting to be filled. Even more amazing was that King wrote this section as if it was perfectly normal for a pharmacist to even be entitled to a break.

Ever since I first entered pharmacy, the issue of being entitled to meal and work breaks has aggravated pharmacists. Think about this for a minute. Have you ever met a pharmacist who, when asked what he or she would change about their job, didn't answer that they wanted a few minutes to rest and recharge?

Are breaks from work really that unreasonable a thing to expect or demand or just take? Do we really need to ask permission to sit down? I think we do. Except I don't believe we need to ask our employers, we need to ask ourselves. And now, with pharmacists filling more prescriptions than ever before, oftentimes without adequate support staff and technicians, we must start giving ourselves permission to step back from the counter to catch our breath.



Arnold Davidov, P.D.
1994-1995 MPhA President

The California Pharmacists Association recently published a well-thought out document of employee pharmacist rights and responsibilities. Yes, meal and work breaks are included along with a variety of other important workplace issues. The MPhA Board of Trustees is reviewing this document to see if it is something that we can use as a springboard for our own policies. The Board of Trustees recognizes that employee pharmacist issues are an area of growing importance and an area that must be explored.

And speaking of exploring, hustle down to the library and pick up a copy of Stephen King's *Insomnia*. Maybe you can read it on your lunch break.

MP

The 1995 Survey of Pharmacists' Salaries

How Do You Measure Up?

*Monica White, Fourth Year Student
UMAB School of Pharmacy*



very two years, the Maryland Pharmacists Association conducts a randomized survey to

determine the level of pharmacist salaries and benefits in Maryland. As part of my rotation with the Association headquarters, I was responsible for coordinating and conducting the 1995 survey.

In mid-January, 536 Maryland licensed pharmacists were mailed a two-page survey that asked questions about their salary, benefits, and overall job satisfaction. These pharmacists were randomly selected from both members and non-members of the Association. Of the total mailed, 195 surveys were returned, representing a 36.3% response rate; this is two percentage points more than the last survey conducted in 1992.

Out of the 195 surveys returned, 16 were eliminated because the pharmacists reported that they were either retired or no longer practicing in the profession. There were 104 male

(59.4%) and 71 female (40.5%) survey respondents. In 1992, the number of female survey responses was only slightly more than 30 percent.

Part of the survey asked the pharmacists for their highest earned educational degree. More than 92 percent hold a Bachelor of Science in Pharmacy. Seven responders hold a Pharm.D. degree, four hold a Master's, and one a doctorate. Interestingly, 34 of the total respondents -- almost one-fifth of the total -- have completed a residency program as part of their education.

Average Yearly Income for Full-Time Pharmacists

| Age | 20-30 | 31-40 | 41-50 | >50 |
|--------|----------|----------|----------|----------|
| Female | \$53,000 | \$50,800 | \$58,400 | \$54,300 |
| Male | \$52,500 | \$62,900 | \$67,400 | \$63,500 |

In compiling the results of the 1995 survey, we tallied and compared the responses by type of practice, position, age, and sex. The chart above summarizes the average yearly income in dollars across all practice settings by both age and sex.

The average salary for female pharmacists of all ages was \$52,684 as compared to \$48,393 reported in the 1992 survey. This represents an increase of 8.8 percent in salary over three years. The average salary for male pharmacists of all ages was \$63,371 in 1994 as compared to \$64,128 in 1992. This represents an actual decrease of 1.2 percent over three years.

Salary and benefit breakdown by practice type and job position are shown on the following page. When examining salaries by job position, independent pharmacy owners had the highest average annual salaries of all pharmacists (\$85,000), followed by hospital pharmacy Directors (\$66,800). At the bottom of the heap? staff or employee pharmacists with an average annual salary of \$53,300. But if you're a staff or employee pharmacist, don't feel too bad. When compared with the 1992 survey results, salaries for this category increased a whopping 14.4 percent (up from \$46,575).

If you're looking to change your practice setting, take a look at long-term care or institutional pharmacy practice. The average salary paid there is the highest of all settings (\$66,100). Coming in second is nuclear pharmacy, paying an average salary of \$64,700.

The survey also asked whether the respondent worked full or part-time. Eight percent of the female pharmacists are part-timers while nine percent of the males work part-time, somewhat refuting that old misconception that women pharmacists only work part-time in the profession. Interestingly, when these part-time surveys were examined more closely, the majority (60%) of female part-timers were between 20 and 30 years old. The male part-timers (50%) were more than 50 years old.

Perhaps the saying that "money isn't everything" should be applied to chain pharmacy practice. Chain pharmacists reported receiving more benefits more often than either independent or hospital pharmacists. For example, 91% of the chain pharmacists responding to the survey reported that they received medical benefits (health insurance). Compare that to 86% of the

hospital pharmacists and only 69% of the independent pharmacists. Chain pharmacists were also more likely to receive dental insurance, paid holidays and personal business days, maternity and/or paternity benefits, vision insurance, and to

be participants in a profit-sharing plan. Although their average salary was significantly higher than most other settings, independent pharmacists didn't fare well when it came to benefits. Less than 20 percent reported receiving maternity and/or paternity leave, vision coverage, or profit-sharing from their employer. Less than half of independent pharmacists have paid holidays and personal business days. Curiously, while everyone reported having at least *some* vacation time as part of their standard compensation package, one hospital pharmacist reported that he didn't get any vacation time. It was unclear whether he just missed the question or if he needs to change employers.

The chart of benefits on page seven only includes the three largest categories of pharmacist employers (chain, hospital and independent); responses from pharmacists in other practice settings were too limited to give meaningful figures.

Average Yearly Income by Job Title/Position

| Job Title/Position | Salary |
|--|-----------|
| Staff or Employee Pharmacist (all sites) | \$53,300 |
| Manager | \$ 59,900 |
| Owner | \$ 85,000 |
| Supervisor | \$ 61,700 |
| Department Director (hospital) | \$ 66,800 |
| Assistant Director (hospital) | \$ 58,500 |
| Clinical Coordinator | \$ 54,000 |

Average Yearly Income by Practice Setting

| Pharmacy Practice Setting | Salary |
|---|-----------|
| Long-Term Care and Institutional Pharmacy | \$ 66,100 |
| Independent Community Pharmacy | \$ 62,300 |
| Nuclear Pharmacy | \$ 64,700 |
| Government | \$ 58,667 |
| Chain Community Pharmacy | \$ 57,300 |
| HMO and/or Managed Care Pharmacy | \$ 54,600 |
| Hospital Pharmacy | \$ 53,000 |

The survey asked several questions about overall job satisfaction, variability of daily activities, plans to change jobs, and intent to stay within pharmacy. Much has been written in national publications about job dissatisfaction, boredom and discouragement with pharmacy as a profession. The design of our survey was to find out whether this was true or not about the pharmacists in Maryland.

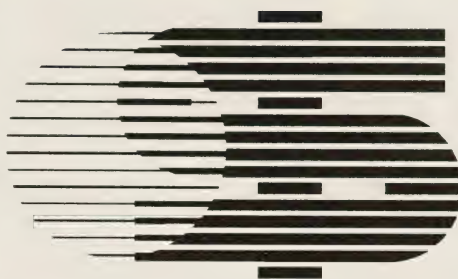
In general, pharmacists gave their jobs pretty high marks when it came to overall job satisfaction. Seventeen percent reported that they were very satisfied, 39 percent were satisfied, and 25 percent were somewhat satisfied. Less than 20 percent of all the responding pharmacists indicated that they were dissatisfied with their current position.

While most pharmacists seem happy with their jobs and the variety of work that they do, a surprising numbers are thinking about moving on. When asked whether they plan to change jobs within the next few years, 44 percent answered "yes."

For those of you polishing your resumé's, take note. That's a substantial increase from 1992 when only 29 percent were looking for new opportunities. Almost 60 percent of those changing jobs plan to stay in pharmacy, 16 percent plan to leave the profession entirely, and 25 percent aren't sure what they want to do. In 1992, almost half of those changing jobs were planning to *leave* the profession to pursue another career.

between five and ten years. Only a third have been in the same position five years or less. In other words, the statistics on job longevity don't support the idea that pharmacists hop from one job to another.

Overall, the MPhA Salary Survey for 1995 shows that pharmacists' salaries and benefits, job satisfaction, and plans for the future remain positive. Even with growing uncertainty about increasing volumes of prescriptions, concerns about



Percentage Receiving Benefits by Practice Setting

| Setting | Medical Insurance | Dental Insurance | Holidays/ Leave | Maternity/ Paternity | Vision Insurance | Profit Sharing | Raises & Bonuses |
|-------------|-------------------|------------------|-----------------|----------------------|------------------|----------------|------------------|
| Independent | 69% | 26% | 48% | 10% | 17% | 19% | 45% |
| Chain | 91% | 87% | 81% | 51% | 66% | 70% | 30% |
| Hospital | 86% | 81% | 81% | 50% | 40% | 33% | 57% |

When asked whether their position gave them a variety of responsibilities and duties, a way of assessing boredom and possibly a lack of professional challenge, the majority of respondents (52 percent) indicated that they had "much" variation. Twenty-eight percent reported that they had "some" variation. Almost a fifth of the pharmacists (18 percent) though reported that they had "little" variation in the daily duties or routine.

If you're an employer and are now looking at your employee pharmacists with a worried eye, take heart. Whether pharmacists actually change jobs as much as they might *want* to is open to debate. For example, almost 40 percent of pharmacists in practice for more than 20 years have kept the same job for at least 20 years. For those with 16 to 20 years of practice, almost a quarter have worked in the same place for more than 10 years, and almost a half have stayed where they are

reimbursement, the challenges of incorporating pharmaceutical care, and changing professional roles Maryland pharmacists are doing well economically. **MP**

Author's Notation

A very sincere "thank you" to each of the pharmacists who took the time to complete and return the MPhA salary survey. Also, I would like to extend my appreciation to the MPhA/ELP students who helped design the survey, copy the materials and stuff the envelopes -- Jeff Brewer and Deborah Glaudin.

The "MP" Profile

This is the second in a series of interviews with the leaders of the Maryland Pharmacists Association. This month, we profile MPhA Trustee Gerard (Jerry) Herpel.

MP: Tell us something about yourself.

Herpel: I guess you could describe me as a frustrated jock. When I graduated from high school in Baltimore, I was asked to try out for the Baltimore Orioles and the Pittsburgh Pirates. Unfortunately, my skills in chemistry far exceeded my pitching arm. Because I did some PEP rotations in Allegany and Garrett County and really liked the pace and peace of Western Maryland, I moved here after graduating from pharmacy school in 1982. After working for a chain and doing relief work, I decided to open my own pharmacy by Deep Creek Lake in 1986.

MP: Good things seem to come in three's for you. You and your wife Betsy have triplets. You drive three hours back and forth to MPhA Board meetings. You've been a Trustee for three years. Where do you find the time?

Herpel: I make the time. And, I guess I feel that being involved in MPhA is important because I'm not the kind of person to just sit on the sidelines and let other people decide what's going to happen to me, my profession or my business. I think that's what appeals to me about being an independent pharmacist. I call the shots. I make the decisions. I'm responsible. It also helps that my wife let's me go to the meetings.

MP: You're also very involved with NARD -- serving on a steering committee, being interviewed for their publications, etc.. What value do they bring to your professional and business activities?

Herpel: I'm involved with MPhA because things that happen in Maryland affect me. I'm involved with NARD for the same reason, just in a broader sense. NARD represents my specific interests as a pharmacist,

as an independent practice owner, and as a small businessman. They're the voice for my particular niche in pharmacy.

MP: What's the biggest challenge for you as a businessman?

Herpel: Keeping my profit margins from shrinking. We've become a heavily regulated profession under the control of barely or non-regulated entities. And if I can't maintain my profit level, that means my family suffers. I don't want that to happen.

MP: What's the biggest challenge to you as a pharmacist?

Herpel: The future. Our profession is changing. We're trying to go from being tied to product to being a provider of services and knowledge. The thing is, most of us aren't sure how (or if we should) let go of working with that product. Especially when those services that we are now trying to charge for have been given

away as part of the product. Try explaining that to a patient or to an insurance company. We pharmacists have a lot of work to do in the next couple of years.

MP: What would you tell non-members about being involved in a professional association?

Herpel: If pharmacy is to survive, we need to have one big voice shouting on our behalf. We can't do it with 1,000 little voices. Associations bring those little voices together.



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Litigation Update

Warning Unforeseeable Users

David B. Brushwood, R.Ph., J.D.

It is well known that dispensed medications are not always used by the patient to whom they were dispensed. When a non-patient borrows a patient's medication, or uses a patient's medication by mistake, questions may arise as to the liability of pharmacists or physicians for harm caused to a non-patient due to his or her use of the medication.

Such a case was recently resolved by the Supreme Court of Tennessee. The facts, as described by the court, disclosed that a patient was prescribed and dispensed glyburide, without being counseled by either the physician or pharmacist regarding the risks of the medication, such as the symptoms of hypoglycemia.

The patient's adult grandson was visiting, and the grandson began to suffer from flu symptoms. The grandmother advised her grandson to take some aspirin, which were on the top of the refrigerator. The grandson took glyburide tablets by mistake, apparently believing them to be aspirin, and he suffered serious consequences of hypoglycemia. The grandmother did not recognize the grandson's hypoglycemia, allegedly because she had not been told how to recognize symptoms.

In the litigation that followed, the key question was the duty to warn, and the foreseeability of harm to the grandson. The court determined that the pharmacist and physician both had a duty to warn the patient of the hazardous effects of this medication. In this regard, the case stands as further evidence of the well developed trend to recognize a duty for pharmacists to warn patients about the risks of drug therapy.

The firm recognition of a pharmacist's duty to warn patients is an important aspect of this case. However, the key issue in the case was the pharmacist's duty to the *grandson*, not the patient.

The court ruled it was not reasonably foreseeable that an adult house guest will reach high upon a refrigerator, take down a bottle of prescription medication clearly belonging to someone else, ingest several of the tablets therein without the knowledge and permission of the owner of the prescription medication. Therefore, the duty to warn did not extend to the grandson, and the case was dismissed.

MP

Based on: *Pittman v. The Upjohn Company*, 1994 Westlaw 663372 (Tenn. November 28, 1994). Copyright 1995, David B. Brushwood. All rights reserved. Reprinted from *Dickinson's Pharmacy*, February, 1995.

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■ **No black box warning regarding
torsades de pointes type arrhythmias**

■ **Well-tolerated adverse event profile**

In controlled clinical trials using the recommended dose of CLARITIN-D Tablets (n=1023), the most commonly reported adverse events included headache (19%), insomnia (16%), dry mouth (14%), somnolence (7%), and nervousness (5%). With the exception of dry mouth and insomnia, the incidence of reported adverse events was similar to placebo.

■ **Contraindications**

Narrow-angle glaucoma, severe hypertension, monoamine oxidase inhibitor therapy, urinary retention, and severe coronary artery disease

■ **Precautions**

Use judiciously in patients with: hypertension, ischemic heart disease, hyperthyroidism, diabetes mellitus, increased intraocular pressure, prostatic hypertrophy, and in nursing mothers.

CLARITIN-D Tablets should generally be avoided in patients with hepatic insufficiency, and the dosage of CLARITIN-D Tablets should be reduced in patients with renal insufficiency.

Please see following page for brief summary of Prescribing Information.

New, b.i.d.

Claritin-D

(loratadine 5 mg and pseudoephedrine sulfate, USP 120 mg)

Extended Release Tablets

**Clear Benefits
From Start to Finish**

New, b.i.d.

Claritin-D[®]

(loratadine 5 mg and pseudoephedrine sulfate, USP 120 mg)

Extended Release Tablets

Clear Benefits From Start to Finish

CLARITIN-D

brand of loratadine and pseudoephedrine sulfate, USP
Long-Acting Antihistamine/Extended Release Decongestant Tablets

BRIEF SUMMARY (For full Prescribing Information, see package insert.)

CAUTION: Federal Law Prohibits Dispensing Without Prescription

INDICATIONS AND USAGE: CLARITIN-D Tablets are indicated for the relief of symptoms of seasonal allergic rhinitis. CLARITIN-D Tablets should be administered when both the antihistaminic properties of CLARITIN (loratadine) and the nasal decongestant activity of pseudoephedrine are desired (see CLINICAL PHARMACOLOGY).

CONTRAINDICATIONS: CLARITIN-D Tablets are contraindicated in patients who are hypersensitive to this medication or to any of its ingredients. This product, due to its pseudoephedrine component, is contraindicated in patients with narrow-angle glaucoma or urinary retention, and in patients receiving monoamine oxidase (MAO) inhibitor therapy or within fourteen (14) days of stopping such treatment (see **Drug Interactions** section). It is also contraindicated in patients with severe hypertension, severe coronary artery disease, and in those who have shown hypersensitivity to pseudoephedrine. CLARITIN-D Tablets should generally be avoided in patients with hepatic insufficiency. Manifestations of patient idiosyncrasy to adrenergic agents include: insomnia, dizziness, weakness, tremor, or arrhythmias.

WARNINGS: CLARITIN-D Tablets should be used with caution in patients with hypertension, diabetes mellitus, ischemic heart disease, increased intraocular pressure, hyperthyroidism, renal impairment, or prostatic hypertrophy. Central nervous system stimulation with convulsions or cardiovascular collapse with accompanying hypotension may be produced by sympathomimetic amines.

Use in Patients Approximately 60 years and Older: The safety and efficacy of CLARITIN-D Tablets in patients greater than 60 years old have not been investigated in placebo-controlled clinical trials. The elderly are more likely to have adverse reactions to sympathomimetic amines.

PRECAUTIONS: General: Because the doses of this fixed combination product cannot be individually titrated and hepatic insufficiency results in a reduced clearance of loratadine to a much greater extent than pseudoephedrine, CLARITIN-D Tablets should generally be avoided in patients with hepatic insufficiency. Patients with renal insufficiency (GFR < 30 mL/min) should be given a lower initial dose (one tablet per day) because they have reduced clearance of loratadine and pseudoephedrine.

Information for Patients: Patients taking CLARITIN-D Tablets should receive the following information: CLARITIN-D Tablets are prescribed for the relief of symptoms of seasonal allergic rhinitis. Patients should be instructed to take CLARITIN-D Tablets only as prescribed and not to exceed the prescribed dose. These tablets should also be advised against the concurrent use of CLARITIN-D Tablets with over-the-counter antihistamines and decongestants.

This product should not be used by patients who are hypersensitive to it or to any of its ingredients. Due to its pseudoephedrine component, this product should not be used by patients with narrow-angle glaucoma, urinary retention, or by patients receiving a monoamine oxidase (MAO) inhibitor or within 14 days of stopping use of an MAO inhibitor. It also should not be used by patients with severe hypertension or severe coronary artery disease.

Patients who are or may become pregnant should be told that this product should be used in pregnancy or during lactation only if the potential benefit justifies the potential risk to the fetus or nursing infant.

Drug Interactions: No specific interaction studies have been conducted with CLARITIN-D Tablets. However, loratadine (10 mg once daily) has been safely coadministered with therapeutic doses of erythromycin, cimetidine, and ketocazole in controlled clinical pharmacology studies. Although increased plasma concentrations (AUC 0-24 hrs) of loratadine and/or descarboethoxyloratadine were observed following coadministration of loratadine with each of these drugs in normal volunteers (n=24 in each study), there were no clinically relevant changes in the safety profile of loratadine, as assessed by electrocardiographic parameters, clinical laboratory tests, vital signs, and adverse events. There were no significant effects on QTc intervals, and no reports of sedation or syncope. No effects on plasma concentrations of cimetidine or ketocazole were observed. Plasma concentrations (AUC 0-24 hrs) of erythromycin decreased 15% with coadministration of loratadine relative to that observed with erythromycin alone. The clinical relevance of this difference is unknown. These above findings are summarized in the following table:

Effects on Plasma Concentrations (AUC 0-24 hrs) of Loratadine and Descarboethoxyloratadine After 10 Days of Coadministration (Loratadine 10 mg) in Normal Volunteers

| | Loratadine | Descarboethoxyloratadine |
|---------------------------|------------|--------------------------|
| Erythromycin (500 mg Q8h) | +40% | +46% |
| Cimetidine (300 mg QID) | +103% | +6% |
| Ketocazole (200 mg Q12h) | +307% | +73% |

There does not appear to be an increase in adverse events in subjects who received oral contraceptives and loratadine.

CLARITIN-D Tablets (pseudoephedrine component) are contraindicated in patients taking monoamine oxidase inhibitors and for 2 weeks after stopping use of an MAO inhibitor. The antihypertensive effects of beta-adrenergic blocking agents, methyldopa, mecamylamine, reserpine, and veratrum alkaloids may be reduced by sympathomimetics. Increased ectopic pacemaker activity can occur when pseudoephedrine is used concomitantly with digoxin.

Drug/Laboratory Test Interactions: The *in vitro* addition of pseudoephedrine to sera containing the cardiac isoenzyme MB of serum creatine phosphokinase progressively inhibits the activity of the enzyme. The inhibition becomes complete over 6 hours.

Carcinogenesis, Mutagenesis, Impairment of Fertility: There are no animal or laboratory studies on the combination product loratadine and pseudoephedrine sulfate to evaluate carcinogenesis, mutagenesis, or impairment of fertility.

In an 18-month carcinogenicity study in mice and a 2-year study in rats loratadine was administered in the diet at doses up to 40 mg/kg (mice) and 25 mg/kg (rats). In the carcinogenicity studies pharmacokinetic assessments were carried out to determine animal exposure to the drug. AUC data demonstrated that the exposure of mice given 40 mg/kg of loratadine was 3.6 (loratadine) and 18 (active metabolite) times higher than a human given 10 mg/day. Exposure of rats given 25 mg/kg of loratadine was 28 (loratadine) and 67 (active metabolite) times higher than a human given 10 mg/day. Male mice given 40 mg/kg had a significantly higher incidence of hepatocellular tumors (combined adenomas and carcinomas) than concurrent controls. In rats, a significantly higher incidence of hepatocellular tumors (combined adenomas and carcinomas) was observed in males given 10 mg/kg and males and females given 25 mg/kg. The clinical significance of these findings during long-term use of loratadine is not known.

In mutagenicity studies with loratadine alone, there was no evidence of mutagenic potential in reverse (Ames) or forward point mutation (CHO-HGPRT) assays, or in the assay for DNA damage (Rat Primary Hepatocyte Unscheduled DNA Assay) or in two assays for chromosomal aberrations (Human Peripheral Blood Lymphocyte Clastogenesis Assay and the Mouse Bone Marrow Erythrocyte Micronucleus Assay). In the Mouse Lymphoma Assay, a positive finding occurred in the nonactivated but not the activated phase of the study.

Loratadine administration produced hepatic microsomal enzyme induction in the mouse at 40 mg/kg and rat at 25 mg/kg, but not at lower doses.

Decreased fertility in male rats, shown by lower female conception rates, occurred at approximately 64 mg/kg of loratadine and was reversible with cessation of dosing. Loratadine had no effect on male or female fertility or reproduction in the rat at doses approximately 24 mg/kg.

Pregnancy Category B: There was no evidence of animal teratogenicity in reproduction studies performed on rats and rabbits with the combination at oral doses up to 150 mg/kg (885 mg/m² or 8 times the recommended daily human dosage of 250 mg or 185 mg/m²), and 120 mg/kg (1416 mg/m² or 8 times the recommended daily human dosage), respectively. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, CLARITIN-D Tablets should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known if this combination product is excreted in human milk. However, loratadine when administered alone and its metabolite descarboethoxyloratadine pass easily into breast milk and achieve concentrations that are equivalent to plasma levels, with an AUC_{0-12h}/AUC_{0-24h} ratio of 1:17 and 0.85 for the parent and active metabolite, respectively. Following a single oral dose of 40 mg, a small amount of loratadine and metabolite was excreted into the breast milk (approximately 0.03% of 40 mg after 48 hours). Pseudoephedrine administered alone also distributes into breast milk and is consistently higher than those in plasma. The total amount of pseudoephedrine concentrations in milk are consistently higher than those in plasma. The fraction of a pseudoephedrine dose excreted in milk is estimated to be 0.4% to 0.7%. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. Caution should be exercised when CLARITIN-D Tablets are administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children below the age of 12 years have not been established.

ADVERSE REACTIONS: Experience from controlled and uncontrolled clinical studies involving approximately 10,000 patients who received the combination of loratadine and pseudoephedrine sulfate for a period of up to 1 month provides information on adverse reactions. The usual dose was one tablet every 12 hours for up to 28 days.

In controlled clinical trials using the recommended dose of one tablet every 12 hours, the incidence of reported adverse events was similar to those reported with placebo, with the exception of insomnia (16%) and dry mouth (14%).

REPORTED ADVERSE EVENTS WITH AN INCIDENCE OF ≥2% ON CLARITIN-D IN PLACEBO-CONTROLLED CLINICAL TRIALS

| PERCENT OF PATIENTS REPORTING | | | |
|-------------------------------|---------------------|--------------------------|------------------|
| CLARITIN-D n=1023 | Loratadine n=543 | Pseudoephedrine n=548 | Placebo n=922 |
| Headache | 19 | 17 | 19 |
| Insomnia | 16 | 4 | 3 |
| Dry Mouth | 14 | 4 | 3 |
| Somnolence | 7 | 8 | 5 |
| Nervousness | 5 | 3 | 7 |
| Dizziness | 4 | 1 | 2 |
| Fatigue | 4 | 6 | 3 |
| Dyspepsia | 3 | 2 | 3 |
| Nausea | 3 | 2 | 2 |
| Pharyngitis | 3 | 3 | 2 |
| Anorexia | 2 | 1 | 2 |
| Thirst | 2 | 1 | 1 |

Adverse event rates did not appear to differ significantly based on age, sex, or race, although the number of non-white subjects was relatively small.

In addition to those adverse events reported above (≥2%), the following less frequent adverse events have been reported in at least one CLARITIN-D treated patient:

Autonomic Nervous System: Abnormal lacrimation, dehydration, flushing, hyposensitivity, increased sweating, mydriasis.

Body As A Whole: Asthenia, back pain, blurred vision, chest pain, conjunctivitis, earache, ear infection, eye pain, fever, flu-like symptoms, leg cramps, lymphadenopathy, malaise, photophobia, rinos, tinnitus, viral infection, weight gain.

Cardiovascular System: Hypertension, hypotension, palpitations, peripheral edema, syncope, tachycardia, ventricular extrasystoles.

Central and Peripheral Nervous System: Dysphonia, hyperkinesia, hypertonia, migraine, paresthesia, tremors, vertigo.

Gastrointestinal System: Abdominal distention, abdominal distress, abdominal pain, altered taste, constipation, diarrhea, eructation, flatulence, gastritis, gingival bleeding, hemorrhoids, increased appetite, stomatitis, taste loss, tongue discoloration, toothache, vomiting.

Eye and Biliary System: Hepatic function abnormal.

Psychiatric System: Antralgia, myalgia, torticollis.

Lysaric: Aggressive reaction, agitation, anxiety, apathy, confusion, decreased libido, depression, emotional lability, euphoria, impaired concentration, irritability, parosmia.

Reproductive System: Dysmenorrhea, impotence, intermenstrual bleeding, vaginitis.

Respiratory System: Bronchitis, bronchospasm, chest congestion, coughing, dry throat, dyspnea, epistaxis, halitosis, nasal congestion, sinusitis, sneezing, sputum increased, upper respiratory infection, wheezing.

Skin and Appendages: Acne, bacterial skin infection, dry skin, eczema, edema, epidermal necrolysis, erythema, hematoma, pruritus, rash, urticaria.

Urinary System: Dysuria, micturition frequency, nocturia, polyuria, urinary retention.

The following additional adverse events have been reported with the use of CLARITIN Tablets: alopecia, altered salivation, anisocoria, anaphylaxis, angioneurotic edema, blepharospasm, breast enlargement, breast pain, dermatitis, dry hair, erythema multiforme, emphysema, hepatic necrosis, hepatitis, jaundice, laryngitis, menorrhagia, nasal dryness, photosensitivity reaction, purpura, seizures, supraventricular tachyarrhythmias, and urinary discoloration.

Pseudoephedrine may cause mild CNS stimulation in hypersensitive patients. Nervousness, excitability, restlessness, dizziness, weakness, or insomnia may occur. Headache, drowsiness, tachycardia, palpitation, pressor activity, and cardiac arrhythmias have been reported. Sympathomimetic drugs have also been associated with other untoward effects, such as fear, anxiety, tenseness, tremor, hallucinations, seizures, pallor, respiratory difficulty, dysuria, and cardiovascular collapse.

OVERDOSAGE: Somnolence, tachycardia, and headache have been reported with doses of 40 to 180 mg of CLARITIN Tablets. In the event of overdose, general symptomatic and supportive measures should be instituted promptly and maintained for as long as necessary. Treatment of overdose would reasonably consist of emesis (peccary syrup), except in patients with impaired consciousness, followed by the administration of activated charcoal to absorb any remaining drug. If vomiting is unsuccessful, or contraindicated, gastric lavage should be performed with normal saline. Saline cathartics may also be of value for rapid dilution of bowel contents. Loratadine is not eliminated by hemodialysis. It is not known if loratadine is eliminated by peritoneal dialysis.

In large doses, sympathomimetics may give rise to giddiness, headache, nausea, vomiting, sweating, thirst, tachycardia, precordial pain, palpitations, difficulty in micturition, muscular weakness and tenseness, anxiety, restlessness, and insomnia. Many patients can present a toxic psychosis with delusions and hallucinations. Some may develop cardiac arrhythmias, circulatory collapse, convulsions, coma, and respiratory failure.

The oral LD₅₀ values for the mixture of the two drugs were greater than 525 and 1839 mg/kg in mice and rats, respectively. Oral LD₅₀ values for loratadine were greater than 5000 mg/kg in rats and mice. Doses of loratadine as high as 10 times the recommended daily clinical dose showed no effect in rats, mice, and monkeys.

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Supporting the Profession

Profiles of Pharmacists and Industry

This Month: Schering Laboratories

"We realized a long time ago how important the pharmacy profession is to our companies and to the health care community as a whole," said Frank DiLascia, R. Ph., Vice President of Trade Sales and Pharmacy Development for Schering Laboratories. "In fact, we believe that the health care community *depends* on the pharmacist."

Schering Laboratories and Key Pharmaceuticals have a long tradition of providing support services for the pharmacy profession. For example, Schering has offered pharmacists innovative continuing educational programs for years. Schering also provides speakers to address pharmacy meetings, seminars, and association meetings across the country. Topics range from scientific, medical, and pharmaceutical issues, to the latest in business and management skills.

Another example of Schering's commitment to the pharmacy profession is the Schering Report, an annual examination of issues and concerns that face pharmacists. The report began more than 15 years ago, and has covered such pressing issues as improper patient compliance, and the pharmacist as an OTC consultant. Issues are researched, evaluated, and the results distributed to pharmacists throughout the country.

Schering's latest pharmacy support program is the Pharmacist Response Network (Schering PRN). Introduced in late 1992, the program was developed exclusively to support the pharmacy community with materials and programs designed to address the specific needs of individual pharmacists and their practices. Schering/Key was the first pharmaceutical company to offer such a unique program, according to Bruce Briggs, R.Ph., Schering Laboratories Director of Pharmacy Development. Because of this, Schering PRN quickly became a success.

"Many programs come and go," Briggs pointed out. "But Schering PRN is in its third year and still growing." Over 75,000 members were enrolled by early 1995; the program handled about 15,000 phone calls over a two-year period; and about 400,000 pieces of material from patient information and continuing education, to allergy updates and product benefits and features were shipped.

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Volume I, Drug Information for the Health Care Professional

The most complete drug information available. Volume I provides clinically relevant drug information on more than 6,000 generic and brand name drug products. Drug listings include indications, pharmacology, precaution side effects, dosing and dosage forms.

Item Number : 920155 Price \$109.00

Volume II, Advice for the Patient

An essential resource for patient counseling. Volume II instructs patients on proper use precautions and side effects for their medications. Pages may be photocopied for use as patient hand-outs.

Item Number: 920257 Price: \$ 54.00

Volume III, Approved Drug Products and Legal Requirements

Compiled in this comprehensive volume are federal and state requirements that affect the prescribing and dispensing of prescription drugs and controlled substances, as well as the entire contents of the FDA's "Orange Book."

Item Number: 920359 Price: \$ 98.00

"We felt that pharmacists needed a program that could quickly and easily help them meet their constantly changing role in health care," Briggs continued. "And judging by the pharmacists' response, we were right." With Schering PRN, pharmacists can access through one central source all of Schering-Plough's programs and services, including those of Schering Laboratories, Key Pharmaceuticals, and Schering-Plough HealthCare Products (the company's over-the-counter pharmaceutical and consumer products division).

"Perhaps the program's best feature is that it is one of the most effective communication networks in the industry," Briggs explained. He cited an incident where fast communication prevented a crisis. When a pharmaceutical company made a Class I recall of one of its products because of contamination by microbial organisms, inaccurate reporting by the media caused physicians, nurses, pharmacists, and consumers to mistakenly assume that the product being recalled was the Schering product, Proventil (albuterol sulfate, USP) Inhalation Solution. Every Schering PRN member was notified by FAX and mailgrams that Proventil was not the product being recalled!

"What's exciting about the program is that it's responsive," Briggs said. "This year, we've made changes in what we offer. That's a direct response to pharmacists who told us what they needed."

"More than ever," Briggs stressed, "we believe pharmacists are vital to the health care community and to Schering. And we'll keep putting that belief into action. We'll continue to be committed to the pharmacy profession and offer whatever services and programs we can to help them in their ever changing and crucial role in health care."

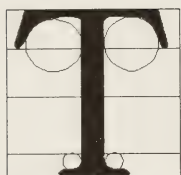
For more information on Schering's goals, objectives and relationship with pharmacy, just talk with your Schering or Key representative. To participate in or access to in the Schering PRN program, simply call (800) SCHERING.

MP

At Issue

Pharmacy, Health Professionals, and the Fiduciary Relationship

Chris Buchar, Pharmacy Student
University of Maryland School of Pharmacy



rust is ineradicable in human relationships.¹ When in states of

special dependence, people are most susceptible to problems that may accompany the latter. To trust and entrust is to become vulnerable and dependent on the values of those being trusted. No where is an "ethic of trust"¹ -- process of accepting to trust -- more challenged than in the fiduciary relationship between the health professional and society.

So challenged, in fact, that Edward Pellegrino in *Trust and Distrust in Professional Ethics* suggests that the central place of trust in professional ethics has recently been so doubted and attacked that an "ethic of distrust" -- a process of choosing not to trust -- has begun to emerge. In the light of such an occurrence, the reassessment of the place that trust holds in the health professions seems imperative, even if such action dictates a redefining of the roles of the professional in the fiduciary

relationship. The physician-patient, physician-pharmacist, and pharmacist-patient relationships will be the topics of examination, beginning with the physician-patient relationship.

In reference to the emergence of an "ethic of distrust," Pellegrino makes clear in his essay that such a stance merely results in a displacement of trust, as well as an indirect undermining of the physicians professionalism. As he states it, "If, ..., we prefer an ombudsman or health care manager to help us make decisions, we merely displace our trust from physicians to some other person." He stresses this paradox to underscore the fact that absolute trust in professionals is inconceivable. This truth is due to the potential conflict between the values of the physician and patient.

Pellegrino points out that there must be a balance between what the physician, with his/her superior medical knowledge, knows is best and what the patient, with his/her own assessments, thinks is best. In this ideal situation, trust no longer entails complete dependence upon the physician's knowledge and judgement, but it now denotes a willingness of the patient to allow the physician to "enable and empower the patient to make their own choice based on the most reliable facts." A sense of the patient's autonomy is then restored without confidence in the altruism of the physician being undermined.

Here is where the role of the pharmacist becomes questioned. As Richard M. Schulz and David B. Brushwood point out in "The Pharmacist's Role in Patient Care," the role of the pharmacist has not yet been adequately defined and therefore "confusion often arises about the scope of their responsibilities..."

With respect to the physician-pharmacist relationship, the pharmacist has traditionally been regarded, as Schulz and Brushwood put it, a "mechanical prescription processor" and thus has no place in the physician-patient relationship; yet, on the other hand, with an "ethic of distrust" emerging, pharmacists may soon be forced into the role of the "ombudsman" and consequently promote such a disruptive "ethic." This would clearly dichotomize the pharmacist and the physician which is the antithesis of what the profession of pharmacy is pushing for.

Schulz and Brushwood argue that pharmacists need to begin to function as "extensions of patients, not of physicians," but not so as to distance themselves, I contend, from the physician. With the surge of pharmacy towards "pharmaceutical care," pharmacists becoming "patient advocates"² is a necessary transition. However, this transition raises a critical question -- Does pharmacist provided drug information interfere with the physician-patient relationship?

According to Schulz and Brushwood, if pharmacists are regarded as patient advocates, patients will be much more inclined to seek counseling and information from their pharmacists than their physicians.

Reasons cited include accessibility, levels of integrity, and social trust. Assuming this is the case, the question of interference arises. If the information given by the pharmacist is consistent with that of the physician, no

interference exists. However, where the opposite is true, the physician-patient and the physician-pharmacist relationships suffer. This scenario may occur more often than not.



Ademantus. "I wonder men dare trust themselves with men."

Timon of Athens, 1.2.43

According to a report by Ruth Fader and colleagues, physicians and patients disagree on the amount of detailed information that should be disclosed and the consequences thereof.³ Thus, what is not disclosed by the physician may be disclosed by the pharmacist. The critical question that surfaces then is, how much information does the patient really need to have. Hence, the pharmacist-patient relationship.

As in the ideal physician-patient relationship, autonomy must exist for the patient in his/her relationship with the pharmacist, but the autonomous patient is more apt to question first before trusting and accepting the pharmacists advice. As patient advocates, then, pharmacists need to support patients' choices based on those patients' judgement on an informed consent, right?

Not necessarily, as this point brings me full circle in my contention. For trust to remain central in the health professions, the role of pharmacy need now be adequately defined. This defining process will continue as pharmacy continues its transition and will ultimately require the joining of forces, so to speak, of

pharmacists and physicians on proper drug therapy, cost effectiveness, etc. But we need a place to begin, a beginning that will ensure the physician's altruism, the patient's autonomy, and the pharmacist a role.

I certainly do not have the answer, but suggest that the beginning may lie with the pharmacist and physician collaborating to define what constitutes the patient's autonomy. Schulz and Brushwood contend that "information may not be withheld to avoid harm to the patient, but only when disclosure would harm the process of decision making." If the latter could be agreed upon, pharmacist as patient advocate would not interfere with the physician-patient relationship and the transition to pharmaceutical care will have a sound beginning.

MP

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We Get Complaints

Melvin Rubin, P.D., Secretary and Commissioner
Theodore Litwin, J.D., Consumer Commissioner
Maryland State Board of Pharmacy

Dean Martin used to say "Keep those cards and letters coming, folks". The Board of Pharmacy would prefer that pharmacists stop certain types of letters from coming.

If the growing number of consumer complaints filed with Maryland Board of Pharmacy is any indication, it appears that the ABC PrimeTime pharmacy exposé sensitized patients to feel that they shouldn't overlook a prescription error. More importantly, these complaints show that consumers aren't willing to let the pharmacist shrug errors off either.

An article in a recent Board of Pharmacy *Newsletter*, sent in conjunction with the National Association of Boards of Pharmacy (NABP), deals with mistakes made by pharmacists. This article will adjunct it by explaining to you how the Board processes complaints.

The Board receives complaints by phone, mail, or personal visits. In order to get the complete information about each complaint, a four-page "Complaint Form," showing the name, address and phone number of the Board of Pharmacy is sent to the complainant for completion and return.

The Board will not take action on *oral* complaints unless there appears to be an urgent public risk if action was not taken immediately.

We are charged with investigating complaints against any person or firm engaged in the manufacturing, packaging, or distribution of prescription drugs in Maryland. Information about persons the consumer believes are not properly licensed is solicited by the Board also. We are required to investigate and respond to any written complaint.

The Board will not handle or resolve complaints concerning billing, pricing, third-party coverage, reimbursement, or similarly purely economic matters where the facts do not appear to support a claim of fraud or misrepresentation. However we refer such complaints to the appropriate unit in the Consumer Protection Division of the

Attorney General's Office and notify the consumer that we have done so.

A handicapped person, who cannot write is encouraged to make an appointment to give their complaint in person.

After a consumer sends in a complaint on the appropriate form, we acknowledge receipt in writing and examine the complaint. The information we request on the "Complaint Form" includes:

- Their name, address, phone number,
- Name of person preparing the form,
- Name of pharmacist(s) named in the complaint,
- Address of pharmacy, manufacturer, or distributor.
- Information about whether they sent the complaint to any other agency,
- Information from the prescription label if appropriate.
- Date of occurrence.
- The exact nature of complaint
- Whether you discussed the complaint with the pharmacist or firm.
- Names and addresses of witnesses, if appropriate.
- Question as to whether they will consent to the release to the Board of Pharmacy of any medical records related to the complaint.
- Signature under an affirmation of truthfulness.

If all of the above sounds like the Board is trying to get enough information to make a complete investigation, *you* got the message loud and clear. What happens after that has been described before.

Oops!

Briefly, the person to whom the complaint has been directed is given a chance to give their side of the story, then a pharmacist and consumer member of the Board review the problem to decide whether more action is needed. Our pharmacy compliance officer, Tracy Baroni, may be sent to investigate by herself or with someone from the Division of Drug Control. The case may be considered closed at that point or the Board may consider charges against the licensee.

Some recent complaints have highlighted the need for pharmacists to know pediatric and geriatric dosing guidelines. At least one serious error could have been averted if *more careful thought* had been given to age-related dosing. Complaints about the length of time it takes for a prescription to be filled have been also become more prevalent. More than one irate consumer has recently complained that it took three or four days to get their medication.

Although the Board has no rule about how long it should take to have a prescription filled, try to imagine how you would feel if you had to wait four days for medicine because the pharmacy was out of the drug or because someone repeatedly forgot to deliver it.

Or, worse still, how would you feel if your two year old received an adult dose of medication and had to be flown to Shock Trauma.

Sometimes even the Board of Pharmacy makes mistakes. Charles Tregoe, P.D., J.D., chief of the Maryland Division of Drug Control wrote to correct and clarify some information that appeared in the article on important numbers which appeared in the February issue. Extracts from his letter appear below.....

Numbers and Amphetamine/Methamphetamine Dispensing

In the early 1970's with the enactment of House Bill 89 and the adoption of regulation 10.13.10, it was originally determined by the Maryland Board of Pharmacy, Commission on Medical Discipline, Medical and Chirurgical Faculty of Maryland, and the Division of Drug Control, that one dosage unit consisted of all of the tablets/capsules contained in each dose to be administered. As an example, *sig*: two tabs in the morning, two in the evening and two at bedtime was a total of three dosage units. It continued in this manner until 1988 when the Board of Pharmacy expressed concerns that it should be changed so that each tablet/capsule was a dosage unit. The Medical and Chirurgical Faculty and Drug Control agreed with the Board's concerns. Therefore, using the aforementioned example, rather than being three dosage units, it was changed to be six dosage units (2+2+2). It continues to be this way today. This issue was included in a newsletter from this office to all pharmacies in Maryland dated September 26, 1988.

I would be remiss if I did not mention that much confusion has arisen over the years because of this entire regulation itself and not just the dosage part. In view of this, consideration is being given to repeal Article 27, Sections 285 (a-2) and (b-1) of the Annotated Code of Maryland.

Numbers and Places to Call

Since many such questions on regulations and laws are answered by the drug inspectors of the Division of Drug Control, us the Division as another resource for information. A number that should be readily retrievable is **(410) 764-2890**, the Division's direct number.

At every step along the way in the complaint process at least one of the consumer members of the Board is kept informed to be sure that the pharmacist members comply with our sworn duty -- to protect the citizens of the State.

To paraphrase the Golden Rule -- "**Do unto others as you would have them rate pharmacists in next year's Gallup Poll on consumer confidence in professionals.**"

MP



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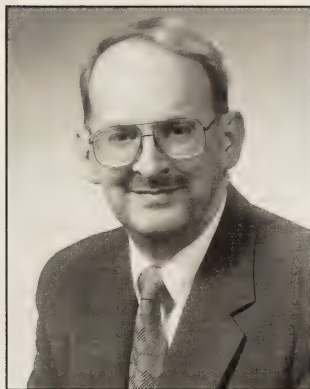
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Interactions...

Nurturing Professionalism in Our Students

Pharmacists share an important responsibility for nurturing professionalism in future generations of pharmacists. It starts in the School of Pharmacy where our faculty take seriously our responsibility to explain and encourage a greater understanding of professionalism by our students. It continues at admissions interviews where applications are probed for their understanding of what it means to be a professional pharmacist. When new students walk in the door of Pharmacy Hall, the first and only course they take for three weeks is a total immersion course entitled Pharmacy Practice and Education. The evolu-



David A. Knapp, Dean
UMAB School of Pharmacy

tion and implications of pharmaceutical care and the philosophical basis upon which our pharmacy curriculum are based are presented. Students and faculty discuss ethical dilemmas and confront the necessity of professionalism in all of the decisions that an autonomous professional makes.

During the second semester of the first professional year, the students enroll in a required course on Ethics in Pharmacy Practice. The philosophy of ethics and the role of formal codes of professional conduct are discussed in the context of resolving conflicting ethical principles. These principles are reinforced as students begin their practice experience in the second professional year with Longitudinal Care. Student/faculty conferences discuss the health care needs of patients

and the necessary actions that pharmacists must take to help meet their total needs. There are many other places in the formal didactic curriculum that ethics and professionalism are raised and dissected. These include the first-year course in the Context of Health Care, the second-year course in Pharmacy Practice Management, and the patient-centered discussions that form the core of Integrated Science and Therapeutics in the third year. The relationship between professionalism and law and regulation is treated during the fourth year.

Perhaps the most important reinforcement students receive of what they have learned is during the experiential program. Now 1500 clock hours long, the program brings each student into contact with over a dozen practitioner-faculty, usually on a one-on-one basis. They say a picture is like a thousand words--well, a week on rotation observing real pharmacists dealing with real patients is worth many hours in the classroom! During the experience program, the concepts carefully built up over years of study can either be strengthened by a good example -- or demolished in a careless moment by an unthinking practitioner. Pharmacists shape behavior by their actions every day they work or talk with students.

A valuable component of nurturing professionalism is the opportunity that some of our students have to spend a month-long rotation in the staff offices of the Maryland Pharmacists Association. The issues that MPhA deals with everyday are directly concerned with the concepts of professionalism in the practice of pharmacy. Thus, David Miller, his staff, and the many volunteer leaders who interact with our students during these rotations are doing much more than giving a flavor of the association world. They are offering a large dose of what professionalism really means to practicing pharmacists. The lessons are of incalculable value.

Oath of A Pharmacist

*I vow to devote my professional life to
the service of all humankind through the
profession of pharmacy.*

*I will consider the welfare of humanity
and relief of human suffering my primary
concerns.*

*I will apply my knowledge, experience,
and skills to the best of my ability to
assure optimal drug therapy outcomes
for the patients I serve.*

*I will keep abreast of developments and
maintain professional competency in my
profession of pharmacy.*

*I will maintain the highest principles of
moral, ethical, and legal conduct.*

*I will embrace and advocate change in
the profession of pharmacy that
improves patient care.*

*I take these vows voluntarily with the full
realization of the responsibility with
which I am entrusted by the public.*

American Association of Colleges of Pharmacy

The very last thing that our students do before graduating, is to stand and publicly take the Oath of the Pharmacist. This oath characterizes the underlying philosophy of our curriculum at the School of Pharmacy. It articulates the finest ideals of the pharmacist as a health professional.

MP



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Continuing Education

New Drug Review: Antidepressant Agents

This lesson reviews the antidepressant drug venlafaxine (Effexor). Its dosage forms and regimens are listed in Table 1. Another antidepressant, fluvoxamine, which had just been approved by FDA at the time of original publication of this lesson, is a serotonin-specific reuptake inhibitor similar to Paxil, Prozac and Zoloft.

The "IS" notation after the drug name signifies that the drug went through the standard FDA approval process.

Depression

Before discussing antidepressants, a short review of depression is in order. All individuals become depressed from time to time due to death of a loved one, loss of a job, etc. For most persons, it is a temporary condition. However, some people need counseling or drug therapy to overcome their low level psychic mood and/or self-esteem.

It has been reported that depression is the most common psychiatric disturbance seen by physicians. As much as 10 percent of the adult population experiences clinical depression at some time.

Depression reportedly occurs nearly twice as often in women than men. For women the peak age range for clinical depression is 35 to 45 years. Depression in men usually occurs later in life. One of the difficulties with the diagnosis and treatment of depression is the subjectiveness of symptoms. This means that there

is no machine or instrument like a sphygmomanometer or MRI that can measure the occurrence or extent of depression. It can only be discovered by observing certain signs and symptoms and then interviewing the patient to see how she or he perceives life overall.

The exact mechanisms of action of psychotherapeutic drugs or how to select the best drug for a given patient have yet to be determined. Therefore, the treatment of depression today is more of an art than a science.

It is known that the thought process is a series of chemical reactions that determine, through sight, touch, sound and the other senses, what is going on in the environment. These sensations are transmitted to the brain along neurons from the periphery, through the spinal cord, to lower parts of the brain and the cerebral cortex. As they pass through the lower brain where

memory and emotions are stored, these messages are matched and compared against one's previous experiences. They are assigned an "I like this," "I don't like this" or "I don't care" component. The impulses then reach the higher centers of the brain and the individual perceives "reality."

This is just one of several theories on thought, but there is much evidence that each individual perceives things differently, because everyone has different life experiences. This theory goes on to state that the thought process is a series of reactions involving dozens, if not hundreds, of chemicals (neurotransmitters). A person's perception of reality depends on the proper "balance" of chemical reactions involved in the thought process.

J. Richard Wuest, R. Ph., Pharm.D.

Professor of Pharmacy Practice, University of Cincinnati

*Thomas A. Gossel, R. Ph., Ph.D., Interim Dean
Ohio Northern University*

A professional development program made possible by an educational grant from **SEARLE**.

At this time, there is no predetermined level for each chemical released during the thought process, or what the relative balance of these chemicals should be. However, given that some neurotransmitters are stimulatory and others inhibitory, this theory concludes that when the neurotransmitters are in balance, the individual is mentally healthy and functioning "normally." When the balance is disturbed, he becomes anxious or depressed, and cannot return to normal functioning without help.

The classic signs of depression are false beliefs, held onto with the conviction that they are correct. Depressed patients have severe feelings of guilt, low self-esteem, high levels of pessimism and self-pity, loss of energy and interest in previously enjoyable activities, and they frequently withdraw from society. Some depressed patients believe suicide is the only answer to their misery. It is estimated that 15 percent of patients with major depression will attempt suicide.

The need for proper diagnosis and treatment is essential since suicide is the eighth leading cause of death in American adults and the second leading cause of death in people between the ages of 15 and 24. This has been estimated to equal approximately 30,000 suicides each year, about 12.5 deaths per 100,000 Americans.

Depression has been subdivided into several forms with the two major groups being bipolar and unipolar. Patients with bipolar depression experience mood swings between major depression and periods of mild but chronic agitation (hypomania) or severe agitation (mania). The latter type is also

New Antidepressant Agent

| Generic Name | Brand Name | Availability |
|---|------------|--|
| Venlafaxine (1S) | Effexor | 25, 37.5, 50, 75 and 100 mg tablets |
| Dosage Regimen | | |
| 75 mg per day in 2 to 3 divided doses titrated up to 225 mg/day | | |

Table 1

referred to as manic-depressive disorder.

The unipolar subtype is major depression with no history of mania or hypomania. It is further subdivided into delusional, depressive symptoms associated with psychotic symptoms; melancholia, classical symptoms of early morning wakening and depressed feelings that may lessen during the day, loss of appetite and weight; atypical, excessive sleeping or eating and being overly sensitive to rejection by another; dysthymia, depressed mood is sporadic or in some patients lasts for several years; and unspecified, depressed persons who do not fit into any of the above groups. Another type of depressive disease is obsessive-compulsive disorder in which affected patients perform normal activities, such as washing their hands, in an obsessive manner and cannot stop.

As stated earlier, there are no objective means to determine whether a person suffers from depression, or what type of depression is present. Diagnosis relies on interviews with the patient to obtain a thorough psychological history. Therapy is then individualized.

A number of methods for establishing a clinical diagnosis of depressive illnesses has been derived. One of the most popular is the "DSM-III-R" method published in the Diagnostic and Statistical Manual of Mental Disorders. Criteria are presented in Table 2.

* Since depression appears to be due to an imbalance of neurotransmitters in the brain, therapy is aimed at restoring the balance.

Nondrug Treatment of Depressive Disorders

Two nondrug methods for treating depression are electroconvulsive treatment (ECT) and psychotherapy. ECT involves administering an electrical stimulus at an intensity sufficient to induce seizures. Prior to therapy, the patient is anesthetized to alleviate discomfort and anxiety, and given muscle relaxants to reduce the chance of muscle damage or bone fractures.

While some individuals consider ECT to be barbaric, others believe it is no different from pushing the reset button on a computer or VCR. ECT is especially beneficial to patients who do not respond or who react adversely to antidepressant drugs, those at a high risk of suicide, and those with cardiovascular

diseases. The frail elderly are also good candidates for ECT therapy.

While the use of ECT for treating depression is not as widespread as drug therapy, it is reportedly the most effective therapy for major depressive disorders. ECT treatment is clinically effective in 80 to 90 percent of patients.

Patient response to drug therapy is about 70 percent, and to placebo approximately 30 percent.

Antidepressant Mechanism of Action

In spite of years of intensive research on antidepressant drugs and administration of millions of doses, their exact mechanism of action has not been elucidated. Several theories have been advanced on how antidepressants and other psychotherapeutic drugs act. Among these are the biogenic amine theory and the newer theory, receptor regulation (up or down).

Diagnostic Criteria for Establishing Major Depressive Illness

1. At least five of the following symptoms present during the same two week period representing a change from previous behavior; at least one of the symptoms is (a) or (b):
 - a) depressed mood
 - b) markedly diminished interest in normal activities
 - c) significant weight loss or gain when not dieting, or decreased or increased appetite
 - d) insomnia or hypersomnia
 - e) psychomotor agitation or retardation
 - f) fatigue or loss of energy
 - g) feelings of worthlessness or inappropriate guilt
 - h) diminished ability to think or concentrate
 - i) recurrent thoughts of death or suicide
2. a) An organic (internal disease) factor that initiated or maintains the problem that cannot be determined.
b) The disturbance is not a normal reaction.
3. At no time during the episode have there been delusions or hallucinations for as long as two weeks in the absence of prominent mood symptoms.
4. The episode is not superimposed on schizophrenia, delusional or other psychic disorders.

Reference: Diagnostic and Statistical Manual of Mental Disorders, 3rd Edition

Table 2

The biogenic amine theory has been popular for the last twenty years. It holds that depression (as well as anxiety and other affective mental disorders) results from a deficiency of relative concentrations of biogenic amines in the synaptic areas between neurons in the central nervous system. Biogenic amines include the monoamines: norepinephrine, dopamine and serotonin.

This theory was advanced after it was learned that drugs which deplete or retard the activity of norepinephrine in the central nervous system (e.g., reserpine, methyldopa) can cause depression. The first group of consistently effective antidepressants increased monoamine activity (i.e., the monoamine oxidase inhibitors). The tricyclic antidepressants and more recently released antidepressant drugs also affect monoamine activity by blocking the reuptake of neurotransmitters into their storage areas inside nerve cells. This causes more of the monoamines to be in the synaptic space between neurons which, in turn, is thought to be responsible for alleviating depression.

Advocates of the biogenic amine theory state that the basis for depression is caused by a deficiency in the synaptic concentration and activity of norepinephrine and/or serotonin. Their belief is further advanced by the fact that different patients obtain differing levels of therapeutic activity from the various antidepressants, and the difference between these drugs is their relative potency in modifying norepinephrine or serotonin concentrations in neuronal synaptic spaces.

Antidepressant Therapy

A major flaw in this theory is the delay in onset of action of psychotherapeutic agents. While these drugs modify monoamine activity within hours after a single dose, therapeutic response takes several weeks. Another problem is that there are a number of reuptake inhibitors with no effective antidepressant activity.

The newer receptor regulation theory states that the psychotherapeutic action of antidepressant and antipsychotic drugs is due to their effect on the number and sensitivity of adrenergic and serotonin (5-HT) receptors on neurons in the brain. Advocates of this theory hold that the change in monoamine levels in the synaptic spaces is important, but not the primary effect of these drugs. Instead, they believe that the increased concentration of monoamines reduces the number of receptor sites on the axons of adjacent neurons.

While it is difficult to understand this theory, it has been found that antidepressants do reduce the total number and sensitivity of alpha-2 adrenergic, beta-adrenergic, and 5-HT₂ receptors in the brain. It takes approximately 2 to 3 weeks for this "down" regulation to occur, which is more in line with the time period needed for full therapeutic effects to be seen. Additionally, it has been shown that while neurotransmitter levels are increased by antidepressants for a few days, they return close to normal after 2 to 3 weeks of therapy.

Treatment of depression was revolutionized in the early 1950's with discovery of the monoamine oxidase inhibitors (MAOI), and with the introduction of the tricyclic antidepressants (TCAs) later in the decade. Over the next 20 years, drugs representing nearly a dozen molecular manipulations of the basic TCA chemical structure were brought to the market.

While all of these agents provided significant therapeutic results, many patients could not tolerate the side effects of drowsiness, constipation, orthostatic hypotension, dry mouth, and blurred vision. This is because TCAs are not selective in their receptor blockade. They also block cholinergic, histamine, alpha-adrenergic, serotonin-1 and serotonin-2 receptors.

TCAs also exert a quinidine-like action on the heart and slow the conduction of electrical impulses through the myocardium. In most patients this is of little consequence. In others, especially in overdose, it can result in fatal arrhythmias.

During the 1980's, several "second generation" antidepressants (i.e., Asendin, Desyrel, Ludiomil, Wellbutrin) were released. These drugs, for the most part, caused fewer anticholinergic side effects than TCAs. However, in some patients, increased extrapyramidal symptoms (Parkinsonism) or seizure activity were a problem.

Over the past few years, the serotonin-specific reuptake inhibitors (SSRI: Paxil, Prozac, Zoloft) have been approved for use in treating depression. As the name of the group implies, they exert specific action on the reuptake of serotonin with no measurable effect on norepinephrine. They lack activity on cholinergic, adrenergic or histamine receptors so they cause far fewer side effects or less cardiac toxicity than previously available antidepressants.

The most recent addition to the family of antidepressants is venlafaxine (Effexor). It reportedly blocks the uptake of serotonin and norepinephrine, and to a lesser extent, dopamine. It has neither cholinergic, histamine or adrenergic blockade properties.

There are many who believe that all commercially available antidepressants are equally effective and that selection of the "best" drug must be individualized and dependent on the patient's response to previous therapy and the avoidance of side effects. If this is true, the newer drugs have a clear advantage over previously available antidepressants. The difference between the SSRI and venlafaxine would be whether the blockade of norepinephrine is beneficial for that particular patient. Generally the only way to determine this is to try the various drugs and see how the patient reacts.

Venlafaxine ("IS")
Trade Name: Effexor

Venlafaxine, the newest entry to the group of antidepressant drugs, is the first of what its manufacturer calls a class of serotonin-norepinephrine reuptake inhibitors. Claims are made that it has a more rapid onset of action than previously available antidepressants. Venlafaxine is as effective as other available antidepressants and causes fewer side effects than TCAs and second generation antidepressants.

Because it increases extracellular levels of norepinephrine, venlafaxine has the potential for increasing blood pressure and heart rate. Therefore it should be used with caution, if at all, in patients with hypertension or other cardiovascular disease.

As with the other antidepressants, venlafaxine is contraindicated concurrently with or within two weeks of monoamine oxidase inhibitors. No direct interaction has been seen, but the contraindication is based on the occurrence of serious, even fatal, reactions in patients receiving other antidepressants concurrently with monoamine oxidase inhibitor therapy.

Side effects reported at the 5 percent or higher level, and not seen at an equivalent level in placebo-treated patients in clinical trials, are sweating, nausea, constipation, anorexia, vomiting, somnolence, dry mouth, dizziness, nervousness, anxiety, tremor and blurred vision.

In clinical trials with males, sexual dysfunction with abnormal ejaculation/orgasm or impotence were observed at 6 percent and 12 percent respectively with Effexor. In comparison, during their clinical trials, similar male genital disorders were seen in 15.5 percent of patients on Zoloft, 12.9 percent of those on Paxil and 1.9 percent of Prozac treated patients.

Effexor is marketed as 25, 37.5, 50, 75 and 100 mg tablets. The recommended initial dose is 75 mg daily either as 25 mg TID or 37.5 mg BID. This can be titrated upward to 225 mg daily based on patient response.

Its manufacturer states that the starting dose should be taken with food. Unfortunately, exactly what the term "starting dose" means is not explained, the reason is not given, and the topic is not addressed in the patient information section of the product's package insert. The manufacturer does state that food has no significant effect on the absorption of venlafaxine.

Additional information useful in counseling patients on the use of Effexor is listed in Table 3. **MP**

To earn one hour of Maryland State Board of Pharmacy approved continuing education credit for this article, simply complete the CE quiz on page 30.

*There is **no charge** for CE credits for members! (Non-members fee: \$5)*

**Patient Information
for Effexor**

Effexor is used to treat depression and other conditions as determined by your doctor.

The manufacturer of Effexor recommends that the starting doses be taken with food.

Some people may experience dizziness, blurred vision or drowsiness from Effexor. If you do, be careful driving or performing hazardous tasks. Alcoholic beverages can increase the drowsiness effect.

Some people may experience lightheadedness while taking Effexor. Sit or lie down at the first signs. Avoid sudden changes in posture. Be careful going up and down stairs.

Do not take nonprescription cough/cold, allergy, sleep aid, or diet medications while taking Effexor without asking your doctor or pharmacist.

It may take several weeks before the full effects of Effexor are noticed. DO NOT change the amount of Effexor taken or stop taking it without consulting your doctor.

Some people may experience dry mouth. If you do, suck on hard candy, chew gum or use a saliva substitute.

If you miss a dose of Effexor, take it as soon as possible. But, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. DO NOT take a double dose, unless directed by your doctor.

Every medication is capable of producing side effects. Most patients experience few or no problems while taking Effexor. However, be sure to tell your doctor if the following occur: nausea, diarrhea, nervousness, irregular heartbeat or pulse, headache, difficulty getting to sleep or urinating, unusual tiredness, hallucinations, skin rash or hives, or any other unusual, bothersome effects.

Table 3

Maryland Pharmacists

The Entrepreneurs

This Month
Harvey Goldberg, Pharmacist
Freedom Pharmacies, Baltimore, Maryland



Harvey Goldberg of Freedom Pharmacies is a pharmacist who actually looks forward to the future. In a time of low reimbursement, "lock out" prescription contracts, and ever increasing threats from mail order pharmacies, this is unusual. To understand Harvey's attitude regarding the future of pharmacy, you need to understand his pharmacy past.

Harvey's father, Milton Goldberg opened a pharmacy on Erdman Avenue. Three years later, he formed a partnership with Abe Berman and opened another pharmacy in Lansdowne. Naturally, Harvey grew up working in the stores, and entered

pharmacy school himself in 1970. He graduated from the University of Maryland in 1973 and immediately went to work in the Lansdowne pharmacy. His job was to re-organize the entire store.

When Harvey was finished, the results were impressive. Abe Berman asked him to do his magic at the Erdman Avenue store and Harvey was happy to oblige. In 1980, Harvey purchased Aero Pharmacy from Jack Barshak. He remodeled the pharmacy and created an office in the rear of the store where he could efficiently run his growing operation. In 1989, he received a call from Harry Lichtman of Drug City. Harry owned a shopping center in Edgemere, and was looking for a buyer for his tenant, North Point Pharmacy. Harvey purchased the store. Since then, he has been eagerly seeking more acquisitions for his growing empire.

One of Harvey's methods for success was "buying out" his closest competitors. He first employed this method in Lansdowne in 1992. After learning that Ben Sulewski was interested in selling his pharmacy, Harvey purchased the store, then closed it down. He was able to successfully transfer most of the prescription volume to his original store. He employed this strategy again in Edgemere in 1993 by purchasing Mike Wagner's Sav-Mor Pharmacy. Once again, he was able to retain the bulk of his former competitor's customer base.



Harvey changed gears in May of 1992 when he was awarded a contract from Hopkins Hospital. This was his first business venture with an institutional client. With his expanded purchasing power, his negotiations with wholesalers helped him offset some of the erosion of third-party payments.


Harvey was at the front of the computer revolution too. His stores have a "neighborhood feel" but have the technology of a major chain drug store. At this time only one of his pharmacies uses point-of-sale, but only because he is testing the system before he installs it in all of his pharmacies. His money order system is electronic and "on line." From his office, he can monitor the operations of all of his stores. He can instantly see profits, volume, and merchandising turnover.

"I am an operations man, not a promotional man," says Harvey. "I have always had a knack for organizing and setting up pharmacies. I leave the promotional aspect of my business to those companies that specialize in promotions." When asked about his "no fear" attitude toward the future of pharmacy he said "I am always looking for new opportunities. I know people have been predicting an end to the neighborhood pharmacy, but I don't buy it. Each year more prescriptions are filled in this country than in the previous year. If you are alert and looking for new opportunities, you will succeed."

Harvey Goldberg has succeeded.

MP

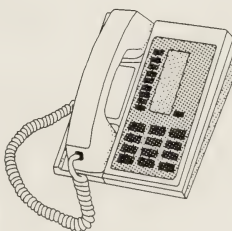
This article is part of a continuing series of our state's entrepreneurial pharmacists. If you have a pharmacist to suggest, please contact the MPhA offices.



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Continuing Education Quiz

April 1995 -- Antidepressants

This month's questions are taken from the article on recently introduced drug therapies for depression that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. There is **no charge** for this quiz for MPhA members (non-members \$5.00). The completed quiz for this issue must be received by September 30, 1995. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name _____

Address _____

City/State/ZIP Code _____

1. Which of the following is a type of bipolar depression?
 - a. Obsessive-compulsive
 - b. Manic-depressive
 - c. Delusional
 - d. Melancholia
2. The biogenic amine theory for mental disorders was advanced when it was discovered that depression is caused by drugs that:
 - a. deplete or retard serotonin activity.
 - b. deplete or retard norepinephrine activity.
 - c. increase or enhance serotonin activity.
 - d. increase or enhance norepinephrine activity.
3. A major flaw in the biogenic amine therapy of mental disorders is:
 - a. the rapid onset of psychotherapeutic drugs.
 - b. norepinephrine is not involved in the thought process.
 - c. the delay in onset of psychotherapeutic drugs.
 - d. serotonin is not involved in the thought process.
4. All of the following statements are true *except*:
 - a. depression reportedly occurs more often in women than men.
 - b. as much as 10 percent of the adult population experiences clinical depression at some time.
 - c. it is believed that the thought process is a series of chemical reactions which determine how individuals perceive reality.
 - d. there are excellent instruments for measuring the occurrence and extent of depression.
5. Venlafaxine reportedly has the *least* activity on which of the following neurotransmitters?
 - a. Acetylcholine
 - b. Dopamine
 - c. Norepinephrine
 - d. Serotonin
6. The group of patients for whom venlafaxine has the greatest potential for adverse effects are those with:
 - a. cardiovascular disease
 - b. diabetes
 - c. glaucoma
 - d. thyroid disease.
7. Patients receiving a prescription for Effexor should be advised not to self-medicate with OTC:
 - a. antacids.
 - b. bulk laxatives.
 - c. pain relievers.
 - d. sleep aids.
8. All of the following are classic signs of depression *except*:
 - a. false beliefs
 - b. constant agitation
 - c. feelings of guilt
 - d. low self-esteem
9. The most effective therapy for major depressive disorders is:
 - a. psychotherapy and guidance training.
 - b. monoamine oxidase inhibitors.
 - c. electroconvulsive treatments.
 - d. serotonin-specific reuptake.

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Services

20% DISCOUNT on awards, plaques, trophies, and engraving to MPhA members. Call Rudy Winternitz, P.D. at Washington Trophy Center, (202) 966-1255.

PHARMACISTS REHABILITATION COMMITTEE For private, confidential referrals call (410) 727-0746 or (410) 706-7513.

Rx LICENSE TAGS are still available! A special benefit "for members only" that costs only a nominal fee. If interested, call Mary Ann at the MPhA offices toll-free, (800) 833-7587.

Placing an Ad

Have something to sell, rent, or trade? Need a pharmacist? Looking for a new position? MPhA members can place a classified ad in *The Maryland Pharmacist* for free. MPhA will remove member ads after six months unless otherwise notified by the member. Non-members may also place a classified ad. The ad placement charge is \$10 for a maximum of 50 words plus 50 cents per word greater than 50. To place an ad, call MPhA at (800) 833-7587.

Next Month's Issue!

Everything
you need to
know about
the 113th
Annual
Convention!

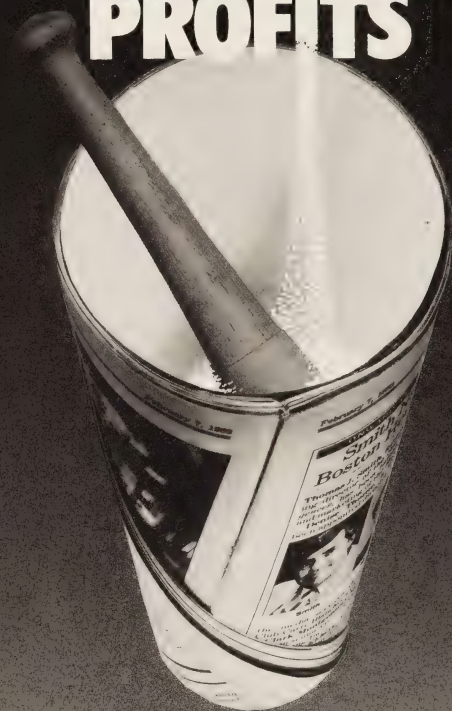


Miscellaneous

WANTED Baltimore pharmacy artifacts and objects (especially local pharmaceuticals, advertising posters and counter top displays) for Baltimore Museum of Industry. Call (410) 727-4808, extension 4.

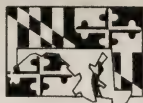


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NEWSLETTER

The Maryland Pharmacists Association

650 Lombard Street

Baltimore, Maryland 21201

(410) 727-0746

Don't Forget!

May 1 is the day for the biennial controlled dangerous substances inventory. Maryland regulations requires that any registrant (pharmacy) who takes this biennial inventory on a different date must notify the Division of Drug Control in *advance* of this decision. Inventories are required to be kept on file in the pharmacy and available for review by inspectors.



Oops, We Did...

In last month's newsletter, we asked for you to alert the MPhA offices if you wanted to participate in the MPhA FAX Alert system. What we forgot to tell you was our FAX number! It's **(410) 727-2253**. Sorry.

MPhA Elections

Candidate statements, ballots and return envelopes for the Association's 1995 elections accompany this issue of the MPhA newsletter. According to our Constitution and Bylaws, all active, dues-paid members are entitled to vote for the officers and trustees of the organization. Please return your ballot in the provided envelope by **April 30, 1995**.

April 1995

This month's newsletter contains an insert from the University of Maryland School of Pharmacy. The views and contents of this insert are those of the School. This insert is presented by MPhA as a means for its members to remain informed about the School's activities.

The MPhA Newsletter is published monthly except during the months of July and August when the issues are combined. For information about any article contained herein, contact MPhA at (410) 727-0746 or toll-free at (800) 833-7587. President: Arnold Davidov, P.D.; Chairman, Board of Trustees: Howard Schiff, P.D.; Production Manager: David Miller, P.D.

Physician Assistants and Prescribing

One of the issues continually monitored by MPhA has been attempts by the physician assistant community to secure prescribing privileges. Two years ago, the Board of Physician Quality Assurance proposed regulations that would have allowed doctors to delegate prescribing to a physician assistant. MPhA, in cooperation with the Board of Pharmacy and the Maryland Society of Hospital Pharmacists, protested this back-door attempt to expand PA's scope of practice without enabling legislation.

Legislation in both the 1993 and 1994 General Assembly to do just that was strongly defeated. No legislation was introduced in 1995. In the meantime, however, the Attorney General reviewed this issue and recently announced a formal opinion that, yes, the physician's Board did have authority to promulgate regulations that would permit delegation of prescribing authority to a physician assistant.

At present, there is no law or regulation that permits physician assistants to prescribe. Nor is there a law or regulation that permits a pharmacist to dispense a prescription written by a physician assistant. If the Board of Physician Quality Assurance does proceed with such a regulation, MPhA, MSHP and the Board of Pharmacy will be working together to ensure that proper safeguards are in place to protect pharmacists and our patients.

(Do you have a practice related question that you would like to see answered in the newsletter? If so, just call the offices at (800) 833-7587 and let us know!)

Morris, Warfield Pass Away

Hospital pharmacist and 1995 candidate for the Maryland State Board of Pharmacy, **Raymond Morris**, died suddenly of a heart condition on March 25. Morris graduated from the University of Maryland in 1972, completed a residency and Masters degree and then a Master of Business Administration in Health Care. He was most recently the Pharmacy Manager at St. Joseph's Medical Center in Towson.

Former MPhA Honorary President **H. Nelson Warfield** died on March 28 of heart failure at the age of 90. Warfield was the former director of professional services of Read Drug. He retired in 1969 after 45 years with the chain after having started as an errand boy, then as a pharmacist, and then a manager. Warfield was a former president and treasurer of the Alumni Association, secretary of the Baltimore Veteran Druggists Association, and was honored in 1988 by the Department of Health and Mental Hygiene for 25 years of volunteer service.



New Member Benefit

To recognize their long-term professional contributions, the Board of Trustees and the Maryland State Board of Pharmacy have developed a Certificate of Recognition for retired members and pharmacists. This Certificate, suitable for framing, acknowledges retirees lifetime of work and dedication to pharmacy. MPhA officers and Board of Pharmacy commissioners will all sign the Certificate.

MPhA's retiree members will automatically receive the Certificate from the offices in late April and early May. Non-member retirees may purchase the Certificate for \$15.

No, No, A Thousand Times No

The Maryland Medical Assistance Program is concerned about the continued use of "89999" dump-codes for prescriber identification numbers. Medicaid policy permits the use of this code only for prescriptions written by physicians who do not participate in the Medicaid program. Any other use is inappropriate. Missing or inaccurate prescriber identification hampers the prospective and retrospective drug utilization review programs.

Recent pharmacy audits have shown that the provider number is on the prescription but that pharmacists are not updating their prescriber or prescription databases to reflect that information. Of especial concern to Medicaid is the use of "89999" on controlled substance prescriptions. The Department is considering a policy change that would prevent submission of prescription claims with this provider identification number.

Pharmacists should make a special effort to double-check or obtain Medicaid provider codes from prescribers. An ounce of prevention on our part can help eliminate the need for unnecessary policies.

Upcoming Health Events

Telephone numbers are provided for additional information and promotional materials.

April

Alcohol Awareness Month (212) 206-6770
National Anxiety Month (201) 763-6392
Stress Awareness Month (410) 732-1900
Organ & Tissue Donor Week (23-29) . (800) 622-9010

May

Better Hearing Month (202) 628-3507
Better Sleep Month (202) 452-9428
Arthritis Month (404) 872-7100
Asthma and Allergy Month (202) 466-7643
Hypertension Month (301) 251-1222
Mental Health Month (800) 969-6642
Nursing Home Week (14-20) (202) 842-4444
Osteoporosis Week (14-20) (202) 223-2226

NARD Criticizes Proposed Policies

In responding to draft policies on Medicare coverage of respiratory products, NARD informed the medical directors of the four Durable Medical Equipment Regional Carriers (DMERCs) that the proposed language "consistently ignores technological advances in providing the most therapeutically appropriate equipment to the patient."

NARD's comments noted that regulations required Medicare Part B beneficiaries to purchase a hand-held metered dose

inhaler in order to be reimbursed for a nebulizer. "This proposed policy sets a terrible precedent in the Medicare program, in that it makes beneficiaries pay for a non-covered item in order to later have Medicare pay for a covered item. In other words, it requires that beneficiaries try an inappropriate, not medically necessary item in order to qualify for the appropriate, medically necessary item."

Also, at issue is the authority of reimbursement agencies like DMERC to place arbitrary restrictions on coverage of products. NARD charges that these attempts must first be legislatively authorized.



CA⁺ Channel Blockers Controversy

In the middle of last month, the media had a field day reporting that hypertensive patients using calcium channel blockers (CCBs) were at an increased risk of myocardial infarction. Pharmacists fielded many calls from concerned patients.

The confusion stemmed from an orally presented abstract during the American Health Association Conference on Cardiovascular Disease, Epidemiology and Prevention. The abstract is from an observational, retrospective case analysis performed among enrollees of the Group Health Cooperative, a Seattle staff model HMO. The complete details of the analysis have not yet been published -- currently lacking is information on patient compliance with therapy, data about the patients' underlying medical conditions, duration of hypertension treatment, etc..



In other words, there is inadequate information available at this time to determine whether or not the study was meaningful. Additionally, there appears to be more risk to patients who abruptly stop their hypertensive therapy without consulting a physician. Patients should be counseled that the findings are

strictly preliminary and to share their concerns about calcium channel blockers with their doctor.

School of Pharmacy News

University of Maryland at Baltimore

Maryland's School of Pharmacy for Over 150 Years

April 1995

Faculty Teams Integrate Basic Science and Therapeutics in Latest Curricular Innovation

For many, it is often difficult to see the apparent application of basic science concepts in everyday life. Yet, pharmacists know that this integration underlies medical and pharmaceutical care. In an innovative new sequence in the Pharm.D. curriculum offered this Spring, the faculty and students are exploring this connection in relation to its crucial role in pharmaceutical care.

The Integrated Science and Therapeutics (ISAT) module begins with a week-long general patient management forum. Designed to expand and reinforce history-taking skills and patient assessment activities, the forum prepares students for the case-based activities that characterize the ISAT series. These case-based activities involve formulating and clarifying a problem, suggesting hypotheses, obtaining relevant data and evaluating solutions; in short, the scientific method. Faculty have developed these activities to center around situations which will help students develop and refine their problem solving, communications, critical thinking skills as well as their ability to transfer their knowledge to new situations. These skills are critical to the provision of pharmaceutical care.

Another innovation of the case-based activities is their logical progression from entry-level pharmacy practice functions to the identification, resolution and prevention of drug-related problems to the appropriate interventions associated with pharmaceutical care. Special attention has been given to long-term care, especially ambulatory care, and the changing needs of the patient to graphically illustrate for the students the fluctuation on health status seen by practitioners over a long period of time. Other patients may appear as cases in both

School of Pharmacy Goes Online with the Internet

If you have computer access to the Internet, you can reach the UMAB School of Pharmacy anytime by contacting us through your World Wide Web site at : <http://www.pharmacy.ab.umd.edu>. After you link to the School of Pharmacy's Home Page, don't be put off by the *under construction* sign. We are in the process of adding information daily! For now, information about school-related events, the Maryland Poison Center, etc. is just a click away. You can also access information on other University of Maryland System schools from our Home Page.

Six Students Make 1995 Who's Who

Mr. Michael J. Barton, Ms. Nancy-Jo Best, Ms. Diane E. Bushman, Ms. Kathleen Hohman, Ms. Melissa Miller, and Ms. Audrey Street will be included in the 1995 edition of *Who's Who Among Students in American Universities*. They have been selected as national outstanding leaders.

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UNIVERSITY OF MARYLAND
AT BALTIMORE

The School of Pharmacy News is produced by the University of Maryland School of Pharmacy which is solely responsible for its content. It is published quarterly in the MPhA Newsletter as a service to MPhA members. If you have any questions or comments regarding the content of this insert, contact Jacquie Lucy, director of public affairs, (410) 706-5893.

Pharmaceutical Sciences Department Has Three New Faculty

UMAB School of Pharmacy welcomes the following new faculty members:

Jane Aldrich, Ph.D., who received her Ph.D. from the University of Michigan (1983), came to UMAB on March 1, 1995 from Oregon State University where she was an associate professor of medicinal chemistry. Her research interest is the design and synthesis of peptide analogues and peptidomimetics.

Stephen W. Hoag, Ph.D., received his Ph.D. in Pharmaceuticals from the University of Minnesota-Twin Cities (1990). Until his appointment at UMAB, he was an assistant professor at Oregon State University. His research areas include sustained release tablet formulation, dissolution testing, mathematical modeling of tablet compaction and computer-aided manufacture.

Jia Bei Wang, M.D., Ph.D., completed her medical degree at the Tong-Ji Medical University in the People's Republic of China (1982) and her Ph.D. in the department of Pharmacology and Experimental Therapeutics at the University of Maryland at Baltimore (1991). She currently is a Post-doctoral Fellow at Johns Hopkins University, School of Medicine, Dept. of Neuroscience and the Laboratory of Molecular Neurobiology, Addiction Research Center, National Institute on Drug Abuse (NIDA).

ISAT Brings Science to Practice

Continued from front page

ISAT and the OTC course to illustrate non-prescription drug therapy.

Typically, lecture style presentations on a scientific concept will be followed by small group discussion of the practical applications of that knowledge as it relates to a case or to one of the patients that they are following in the longitudinal care. Both journal club and week pharmaceutical care rounds are important additions to standard lectures. Classes team faculty from both the science and practice departments to discuss topics ranging from pharmacology, chemistry and kinetics as they relate to clinical management and scientific problems involved. Professors Edward Moreton and Tony Tommasello team to discuss the pharmacology of drugs of abuse, their clinical manifestations and the treatment of addictions in a small group setting.

"My goal is to present students a case scenario and then guide them through its resolution, while encouraging them to think through the clinical issues with good science," says Tony Tommasello, Pharmacy School Associate Professor, and director of the Office of Substance Abuse Studies.

In addition to exploring the scientific aspects of pharmaceutical care, students discuss relevant topics such as population and financial variables which impact on patient's health and compliance to their drug therapy.

As always with the pharmaceutical care model, outcome and intervention are major considerations. Thus, patient education focuses on making the patient aware of how the drug acts for their disease state as well as what behaviors the patient has to adopt in conjunction with taking the medications.

To put the entire course in true perspective, the module ends with an assessment of the individual patient intervention, population intervention, prescriber intervention and system intervention.

Jacquelyn S. Lucy

Pharm.D. Program Continues to Attract a Record Number of Applicants

According to Dr. Robert S. Beardsley, Associate Dean for Student Affairs and Administration, the school has received 620 applications for the 1995 Fall semester.

Post Scripts

- R** Curatek Pharmaceuticals has two new educational charts to help patients recognize the difference between bacterial vaginosis (BV) and other common infections. The increased awareness is hoped to help reduce health risks in women that may result from undetected and untreated BV. The consumer chart, title "Don't Assume It's Yeast" helps women identify the difference between BV, yeast, and trichomonas. Copies of the charts are available by calling: (800) 332-7680.
- R** Abbott Laboratories has begun marketing a new electronic infusion system with three independent lines. The Plum XL3 offers hospitals, alternate care settings, and home infusion services the capability of delivering primary and/or secondary fluids at independently preset rates with automatic piggybacking as needed.
- R** The Health Care Finance Administration (HCFA) has suspended the Federal Upper Limit as of January 19, 1995 for the following products: bacitracin zinc; polymyxin B sulfate 500 units/gram; 10,000 units/gram, ophthalmic 3.5 gm.
- R** MPhA members **Steve Disharoon, Joseph High, Jerry Herpel** and MPhA Executive Director **Dave Miller** attended the NARD Legislative Conference in Washington, DC in late March. Herpel and Miller met with Senators Sarbanes and Mikulski staffers to seek support of Federal House Bill 598 -- the Pharmacist Compounding Preservation Act.
- R** Breckenridge Pharmaceutical, the makers of Prodiem, have prepared a consumer counseling pamphlet on the topic of urinary tract infections called "UTIs, What You Need to Know about Causes, Symptoms, Prevention, and Relief." The tri-fold pamphlet, in packets of 25 with a small cardboard stand, are available for free to any pharmacy or pharmacist which calls (800) 365-3395.
- R** Pennex Pharmaceuticals has changed its name and NDC labeler code. They now trade under the name Morton Grove Pharmaceuticals and the new NDC identification number is 60432. Pharmacists using Pennex products should update their computer drug databases to avoid future claims rejections.

NARD•Lilly Digest Published

The *Lilly Digest*, now a joint project with NARD, has just been published with a summary of 1994 pharmacy performance. Here's a quick look at the figures:

| | <u>National</u> |
|---------------|-----------------|
| Total Sales | \$1,247,955 |
| Gross Margin | 29.3% |
| Net Profit | 3.0% |
| Annual Rx | 37,429 |
| Ave Rx Charge | \$ 26.48 |

Get Along Little Doggie

The 113th Annual Convention is fast approaching. Our theme this year, *A New Frontier for Pharmacy*, reflects a focus on implementing pharmaceutical care in everyday community pharmacy practice. Complete information about the Convention, scheduled for June 19-21, 1995 at the Sheraton Ocean City Resort Hotel, is being provided to all Maryland pharmacists in the May issue of *The Maryland Pharmacist*.



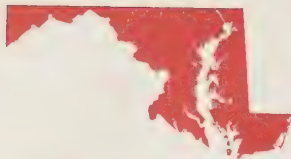
In preparing for the Convention, MPhA wants to remind all members that they have the opportunity to serve as Delegates to the Convention. Delegates debate policy issues during two scheduled business sessions. Members may volunteer for appointment by contacting their affiliated local organization, by calling the MPhA offices at (800) 833-7587, or by indicating their interest on the Convention Registration Forms.

Watch your mail for MPhA's big roundup!

School Studies Interventions

Through an interagency agreement between the Department of Health and Mental Hygiene and the School of Pharmacy's Center on Drugs and Public, a new model to explore the benefits of offering pharmacy services at the site of prescribing rather than "after the fact" at the pharmacy has been implemented. The School has hired two pharmacists, Catherine Fields and Theresa Ng to spend five to fifteen minutes talking to chronically ill Medicaid recipients about their drugs. Fields and Ng take drug histories on patient medication use and makes recommendations on the patient's chart for the physician.

According to **Helen Zuckerman**, principal investigator for the Medicaid grant, the purposes of the program are: to help improve patient health and compliance; assure proper prescribing through pharmacist/physician intervention; and provide physicians with specific information on the most cost-effective medications available. At present the model is in effect at Maryland General, Johns Hopkins, University of Maryland and St. Agnes Hospitals.



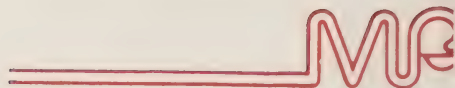
Maryland Pharmacy Event Calendar

- April 1 UMAB/Rx Open House for Prospective Pharmacy Students, (410) 7076-0756 to register.
- April 9 AZO CE Program, 9:30 am, Pikesville Holiday Inn. Call David Banks at (410) 465-5683.
- April 20 **MPhA Board of Trustees Meeting, MPhA Headquarters, 7:00 pm.**
- April 23 CE Program "New Drugs", VA Medical Center/Perry Point, 8:00 am, Call (410) 642-2411, ext 5466.
- April 24-9 NARD Fitting School/Exam (Camp), Milwaukee, WI. Call NARD at (800) 544-7447.
- April 25 UMAB/Rx Alumni Association Meeting, 8:15 pm, Room 740, School of Pharmacy.
- April 26 Eastern Shore CE Program, "Tuberculosis," Rustic Inn, Easton. 8:00-10:00 pm.
- May 8-12 NARD Fitting School/Exam (OTC), Dallas, TX. Call NARD at (800) 544-7447.
- May 8-9 NCPIC 10th Conference on Prescription Medicine Information, Washington, DC. (202) 347-6711
- May 18 **MPhA Board of Trustees Meeting, MPhA Headquarters, 7:00 pm.**
- May 21 AZO CE Program, 9:30 am, Pikesville Holiday Inn. Call David Banks at (410) 465-5683
- May 23 Washington County CE Program, American Legion, 7:00 pm. Call Chris Brown at (301)
- June 4 Washington County Golf Outing and CE. Call Chris Brown at (301)
- June 18-21 **MPhA Annual Convention, A New Frontier for Pharmacy, Ocean City**
- July 13-16 AmeriSource "Celebrate the Music" 9th Annual Trade Show, Opryland Hotel, Nashville, TN
- Oct 20-21 MSHP Annual Seminar, Sheraton Society Hill Hotel, Philadelphia, PA.
- Oct 28 BMAPA Annual Dinner Dance and Awards Banquet, Sheraton Towson

NEWSLETTER

The Maryland Pharmacists Association

650 Lombard Street
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MARYLAND PHARMACIST

May, 1995

Vol. 71, No. 5

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MARYLAND PHARMACIST

The Official Publication of The Maryland Pharmacists Association

May 1995

4 President's Commentary

MPhA President Arnold Davidov invites all Maryland pharmacists to take a look at the New Frontier of Pharmacy at the upcoming MPhA Convention.

5 Continuing Education

This month we present Part VII in our ongoing update of new drugs and drug therapies. Featured are new products for schizophrenia and insomnia. Don't forget to complete the CE quiz on page 30 for credit! It's free for all MPhA members.

14 A New Frontier for Pharmacy

It's time to gather the wagons in a circle! Find out all you need to know about the upcoming 113th Annual MPhA Convention in Ocean City.

18 Good Records Are For Listening

But they're even more important when it comes to an inspection. Board of Pharmacy Secretary Mel Rubin shares some of the Board's expectations of pharmacists.

21 Litigation Update

Regular columnist David Brushwood looks at a recent legal decision that raises the question: are pharmacists health care providers?

22 At Issue

Should pharmacists prescribe? Pharmacy student Carolyn Jones looks at a question that is increasingly asked by the profession.

25 Should Pharmacy Students Work?

A professionwide survey from the School of Pharmacy's Educational Advisory Committee lets you express your thoughts on students and employment.

28 Maryland's Entrepreneurs

Hagerstown pharmacist Chris Brown started out compounding banana splits.

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Articles and editorials that appear do not necessarily reflect the official positions of the Maryland Pharmacists Association and may contain views and opinions for which the authors hold sole responsibility.

Postmaster: Send address changes to MPhA, 650 West Lombard Street, Baltimore MD 21201.

Advertiser's Index

Whenever the opportunity arises, please thank them for their support.

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President's Commentary

There's Just Not Enough Time

Each month, the 20 members of the Maryland Pharmacists Association Board of Trustees meet to discuss issues facing the profession and the Association. Sometimes, our meetings are filled with debate over legislative and regulatory issues that affect every pharmacist in Maryland. At other meetings, we have more philosophical discussions about the future of pharmacy and what we as a professional organization should be doing to meet that future. Of course, our staff updates us on the day-to-day operations of the Association.

Recently, I noticed that attendance at our monthly meetings was declining. At first, I thought that maybe our Trustees were losing interest. No, it wasn't that. In fact, I can't imagine a more dedicated group of pharmacists who willingly volunteer what little time they have to help better their profession. Then I thought that perhaps our meetings were becoming boring. No, it wasn't that either. To be perfectly honest, some of our meetings become quite "spirited."

Finally, I asked some of the Board members what they thought was the problem. Boy, was I surprised at the answer.

It seems that almost half of the MPhA Board members are enrolled in the non-traditional Pharm.D. program at the University of Maryland School of Pharmacy. Sometimes the Board meetings conflict with classes. Sometimes our meetings are the night before a major examination or when a research paper is due.

But, you know, our Board is not unique. The more pharmacists I talk to the more I discover are actively involved in improving their education. Some are taking the Pharm.D. classes. Others attend corporate meetings like the ones that Giant and Rite-Aid hold for their pharmacists. Still others are busy going to local association seminars like the monthly meetings held by the Eastern Shore Pharmaceutical Society or the quarterly meetings sponsored by the Southern Maryland Pharmacists Association. Add to that all

the other education options available to pharmacists and you can surely see why each of us believe that there just isn't enough time during the day to balance work, family, and professional development.

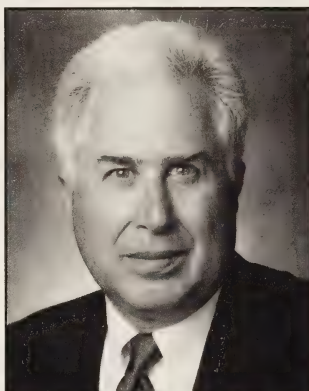
MPhA is trying to make professional development a little easier for our members. Each month, this magazine contains a one-credit continuing education article that is free to all members. Beginning in July, these CE articles will also be ACPE approved as well as Maryland State approved. And, as a special bonus to members, we are enclosing a free two-credit continuing education booklet with this issue of *The Maryland Pharmacist*.

But of all the educational programs, articles, seminars, etc., that MPhA has available to the pharmacy community, the ultimate "don't miss" is our Annual Convention.

For three days in June, you and your family can descend on Ocean City with other pharmacists and their families. While you attend educational programs, your family can enjoy the beach and the Boardwalk. While you earn more than 10 hours of CE credits, your family can take in our Trade Exposition, enjoy Ocean City's premiere resort hotel, shop, etc.. Then, in the evenings, you can all enjoy our receptions, crab feast, and parties.

Seriously, the MPhA Annual Convention is a wonderful opportunity for you to get away from the pharmacy, spend time with your family and colleagues, enjoy the beach, learn, network, and have an all around great time. It's casual, comfortable, and relaxed.

Take a look at pages 14 and 15 to see our Advance Program for the upcoming Convention. Then decide today to come down to the beach on June 19-21. **MP**



Arnold Davidov, P.D.
1994-1995 MPhA President

Schizophrenia is the most common psychotic disorder affecting an estimated two million Americans. As with other mental disorders, schizophrenia is believed to be caused by an imbalance of neurotransmitters in the central nervous system (CNS). The thought process is believed to be a function of manufacture, release, and reaction of numerous chemicals (neurotransmitters) which transmit messages from neuron to neuron in the CNS.

These chemical reactions tell us how to interpret stimuli from within the body and our environment, how to compare them with our previous life experiences, and how to react. When the neurotransmitters (e.g., norepinephrine, dopamine, serotonin, acetylcholine, gamma-aminobutyric acid, endorphins, and many others) are produced and act in the proper balance with each other, we function "normally." When there is an imbalance, the affected person can suffer from different extremes of anxiety or depression.

Schizophrenia can be induced in animals by administering amphetamines, which activate the dopaminergic system in the brain. Subsequently this induced psychosis can be reversed by administering dopamine blocking agents. This has been accomplished successfully in humans, and antipsychotic drugs have been the cornerstone of therapy for schizophrenia. The phenothiazine derivatives are dopamine blockers and have been used in therapy for many years.

New Drug Review: Risperdal and Ambien

J. Richard Wuest, R. Ph., Pharm.D.

Professor of Pharmacy Practice, University of Cincinnati

*Thomas A. Gossel, R. Ph., Ph.D., Interim Dean
Ohio Northern University*

A professional development program made possible by an educational grant from **SEARLE**.

The major problem with their use is the relatively high incidence of drowsiness, orthostatic hypotension, and Parkinson-like extra-pyramidal symptoms (EPS).

When introduced to the market, haloperidol replaced the phenothiazine derivatives to a large extent, but it also causes EPS. Clozapine (Clozaril) has little tendency toward EPS, but its major drawback is the potential for drug-induced agranulocytosis. Risperidone is devoid of significant EPS or agranulocytosis.

Schizophrenia, like other psychotic disorders, is believed to result from excessive release of and activity by dopamine and serotonin in selected regions of the CNS. Unlike many other psychotic disorders, it often begins early in life. This results in a chronic emotional disorder as well as social problems in terms of the family of the affected patient and the cost of treatment.

There are four described types of schizophrenia: catatonic, disorganized, paranoid, and undifferentiated. Basically, the catatonic schizophrenic patient has difficulty moving about and performing simple tasks. The disorganized type is self-explanatory, and the paranoid patient is extremely suspicious of the intentions and actions of others. Undifferentiated schizophrenic patients suffer from both or all of these intermittently.

The psychotic symptoms of patients suffering from schizophrenia include abnormal perception, thought content, and reaction to stimuli. They suffer from hallucinations, illusions, and delusions. Hallucinations involve abnormal auditory disturbances in that the patient hears noises, voices, or music when none are present. Illusions differ from hallucinations in that sensory stimuli are present, but they are misinterpreted. Delusions are inappropriate beliefs held by the patient in spite of reasonable evidence to the contrary.

Patients sometimes bounce between inappropriate and exaggerated responses to normal occurrences (such as laughing hysterically while talking about the death of a loved one), and a condition called "blunting" whereby they do not respond to stimuli that should arouse or depress them. Unfortunately blunting can also result from over-medication with antipsychotics.

Additional symptoms of schizophrenia include being able to converse with others in a manner that seems to be coherent, but does not convey useful information, and long periods of time before the patient responds to questions, to the extreme of being mute and not responding at all.

Traditionally, symptoms of schizophrenia have been divided into positive symptoms and negative symptoms. Foremost among the positive symptoms are abnormal thoughts for the general population such as hallucinations. Major negative symptoms involve the absence of normal response to everyday life such as social withdrawal and lack

New Hypnotic and Antipsychotic Agents

| Generic Name | Trade Name | Availability | Dosage Regimen |
|--------------|------------|---------------------------|--|
| risperidone | Risperdal | 1, 2, 3, and 4 mg tablets | 1 mg BID initially, titrated upward to 4 to 6 mg/day |
| zolpidem | Ambien | 5 & 10 mg tablets | 5 to 10 mg at bedtime |

Table 1

of motivation. One method of diagnosing schizophrenia is the use of the positive and negative symptom scale (PAMSS), presented in Table 2. With older antipsychotic drugs, negative symptoms were more debilitating, but the positive ones responded better to therapy.

Treatment of Schizophrenia

One of the more amazing feats of neuropharmacology is that scientists have been able to identify the actual chemical configuration of physiologic receptor sites and identify subtle differences that cause drugs to stimulate some receptors, but not others. Therefore, drugs can be agonist (elicit the same effect as endogenous neurotransmitters), antagonists (block the action of endogenous neurotransmitters), mixed agonist/antagonists (stimulate some receptors and block others) and selective agonist or antagonists. With the latter, the drug will act on some physiologic receptors, but not others.

This is especially important for antipsychotic drugs because scientists have determined that the same basic chemical receptor configurations are present in some parts of the body, but not others. The classic examples are the histamine receptors. They are present in the connective tissue of the skin, brain, and stomach. However, to those in the brain and skin respond to traditional antihistamines (i.e. diphenhydramine) while those in the stomach respond to cimetidine, famotidine, nizatidine an ranitidine, but not antihistamines. Therefore, they are now referred to as histamine-1 and histamine-2 receptors and antagonists.

The concept is similar with dopamine in that there are dopamine-1 and dopamine-2 receptors in different regions of the brain. Serotonin (5-HT) receptors are even more diversified. The 5-HT₁ receptors are in the walls of blood vessels, 5-HT₂ receptors are in the CNS, 5-HT₃ receptors are in the gastroesophageal plexus and vomiting center (CTZ) of the brain, and 5-HT₄ and 5-HT₅ receptors are scattered elsewhere in the body.

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Blockade (antagonism) of dopamine-2 receptors has been identified as the major factor in reducing the positive symptoms of psychoses. Blockade of the 5-HT₂ receptors is considered to be the major factor in reducing negative symptoms. Prior to the introduction of clozapine, and now risperidone, conventional antipsychotic had been relatively unsuccessful in alleviating the negative symptoms. This is because conventional antipsychotic do not exert appreciable 5-HT₂ blockade.

Risperidone **Trade Name: Risperdal**

Risperidone (ris-PER-i-done) (Risperdal) (RIS-per-dal) is the second dopaminergic/serotonergic blocking agent to be approved for marketing, joining clozapine which was released several years ago. It is indicated for management of psychotic disorders, but like clozapine, it was approved by FDA based on studies demonstrating effectiveness in treating schizophrenia. Risperidone possesses advantage over clozapine and earlier available antipsychotics.

phenothiazines with significantly fewer side effects. Since it has not been linked to agranulocytosis as clozapine has, there is no need for the expensive weekly blood tests required by the latter drug. Risperidone is reported to be effective in approximately 80 percent of schizophrenic patients and considered to be the drug of first choice by most experts.

Side Effects and Dosage

Side effects reported by the manufacturer at the 5 percent or higher level are: insomnia, 23 percent (vs. 19 percent for placebo); agitation, 22 (vs. 20) percent; extrapyramidal symptoms, 17 (vs. 16) percent; headache, 14 (vs. 12) percent; anxiety, 12 (vs. 9) percent; rhinitis, 10 (vs. 4) percent; constipation, 7 (vs. 3); percent; and nausea, 6 (vs. 3) percent.

The usual adult dose of Risperdal is 1 mg twice a day initially, then titrated upward to the optimal dose. The reason for starting with the lower dose is to reduce the potential for orthostatic hypotension secondary to adrenergic blockade. While this occurs rarely, dosages titration minimizes the risk.

Elderly patients and those with significant renal or hepatic disease should be started at an even lower dose and titrated more slowly.

The absorption of Risperdal is not affected appreciably when it is given with or without food. Additional information useful in counseling patients is listed in Table 3.

Positive and Negative Symptom Scale for Schizophrenia

Positive Symptoms

Conceptual disorganization
Delusions
Excitement
Grandiosity
Hallucinations
Hostility
Persecution complex
Suspiciousness

Negative Symptoms

Apathy
Blunted reactions
Difficulty in abstract thinking
Difficulty in flow of conversation
Emotional Withdrawal
Lack of spontaneity
Poor rapport
Social withdrawal

From the Diagnostic and Statistical Manual of Mental Disorders, Third Edition

Table 2

Mechanism of Action

Risperidone exerts dopamine-2 antagonism and 5-HT₂ antagonism. Its highest affinity is for 5-HT₂ receptors, then dopamine-2 receptors. While it has some alpha-adrenergic and histamine-1 blockade activities, these are far less than those with the phenothiazine derivatives. Risperidone is therefore considered to be more effective therapeutically than the

Patient Information for Risperdal

Risperdal is used to treat psychotic disorders and other conditions as determined by your doctor.

Risperdal should be taken with a full glass of water. It can be taken with or without food.

Some people may experience dizziness, blurred vision, or drowsiness from Risperdal. If you do, be careful driving or performing hazardous tasks. Alcoholic beverages can increase the drowsiness effect.

Some people may experience dizziness or lightheadedness while taking Risperdal. If you do, sit or lie down at the first signs of dizziness, avoid sudden changes in posture, and be careful going up and down stairs.

Do not take nonprescription cough/cold, asthma, hayfever, sleep aid, or diet medications without asking your doctor or pharmacist.

Risperdal may make your skin more sensitive to sunlight or sunlamps. Ask your pharmacist about a suitable sunblock product (of at least SPF 15) to reduce exposure problems.

If you miss a dose of Risperdal, take it as soon as possible. But, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose, unless directed by your doctor. If you miss taking your medication for more than 2 days, you should contact your doctor for dosing instructions.

Most patients experience few or no problems while taking Risperdal. However, be sure to tell your doctor if the following occur: unusual anxiety or nervousness, shuffling walk, trembling hands, difficulty in speaking or swallowing, nausea or vomiting, difficulty in sleeping, constipation, or any other unusual, bothersome effects.

Table 3

Insomnia

While nearly everyone experiences sleeplessness on occasion, it has been reported that more than 10 percent of Americans complain of clinical insomnia. Poor night time sleep and resulting next-day drowsiness cause diminished ability to concentrate, impaired memory, failure to complete daily tasks adequately, and interpersonal difficulties.

As with mental disorders, insomnia is believed to be caused by an imbalance of neurotransmitters in the CNS. The sleep-controlling neurotransmitters include acetylcholine, dopamine, gamma-aminobutyric acid (GABA), and serotonin. The major one is GABA which reduces stimulatory impulses from reaching the higher centers of the brain, thus allowing for and maintaining sleep.

Pain, irritation, worry, and emotional upset may interfere with the ability to fall asleep and lead to nighttime awakenings and lighter sleep. Psychiatric disorders (including schizophrenia) also cause insomnia. Other causes include: disruption of the normal sleep pattern (i.e., jet lag, work-shift change); change of environment (e.g., sleeping away from home); sleep apnea (shortness of breath and snoring); nocturnal myoclonus (periodic limb movements during the night); and taking CNS stimulants too late in the day.

Insomnia is especially prevalent in the elderly. The National Institutes of Health has reported that more than one-half of persons over age 65 who live at home; more than two-thirds of residents in long-term care facilities, experience some type of sleep disorder.

Treatment of Insomnia

Before using hypnotics, it is recommended that other measures for treating insomnia be tried. These include withdrawal of excessive or inappropriate drugs and patient education on good sleep hygiene and stress management.

Currently, drug therapy for insomnia is based on drugs that enhance the activity of GABA, the benzodiazepine derivatives, and now zolpidem. GABA, as alluded to earlier, is an extremely important inhibitory neurotransmitter in the brainstem and foreparts of the higher centers of the brain. When released from storage, it reacts with its receptor sites thereby reducing CNS neuronal activity, thus inducing and maintaining sleep.

GABA acts by enhancing the entry of chloride ions into neurons. High intracellular chloride levels raise the threshold for depolarization. This is the process by which impulses pass along neurons causing them to fire and release their neurotransmitters. This means that GABA prevents the movement of stimulatory sensations upward to the cerebral cortex where the thought process takes place. With reduced stimulation from the environment, consciousness is lessened, the individual relaxes and sleep follows.

Zolpidem *Trade Name: Ambien*

Zolpidem (Zol-pi-dem) (Ambien) (Am'-bi-en) is the first imidazopyridine hypnotic to be approved for marketing in the U.S. Its mechanism of action is similar to the benzodiazepine derivatives with some important differences.

Zolpidem, like the benzodiazepine derivatives, links up with omega receptors on neurons. This sets off chemical reactions with the cell that make it easier for GABA to bind with its receptor sites. The net result is enhanced GABA activity and the promotion and maintenance of sleep.

As with other physiologic neurotransmitter/receptors systems, there are three subtypes of omega receptors. The Omega-1 receptors are most associated with sleep and are concentrated in an area of the brainstem called the locus ceruleus or sleep center. Omega-2 receptors are more prevalent in the higher centers, and the Omega-3 receptors occur mainly at the myoneural junctions where neurons meet and stimulate muscle tissue.

Therefore, drugs that act as Omega-1 receptors are hypnotics, those that react with Omega-2 receptors are anticonvulsants, and Omega-3 agonists are muscle relaxants. Most of the benzodiazepine derivatives act at all three omega subtype receptors.

Zolpidem is different in that it only has significant affinity for Omega-1 receptors. Because of this, it has no anticonvulsant or muscle relaxant activity and is specifically a hypnotic agent. This

has major implications relating to its potential for abuse and addiction. While the DEA classifies all hypnotics as scheduled substances, there is evidence that the addiction potential for benzodiazepine derivatives is related to their ability to react with both Omega-1 and Omega-2 receptors. Zolpidem is a schedule IV controlled substance. Several studies have demonstrated that it has limited abuse potential and many physicians agree.

Side Effects and Dosing

Side effects for Ambien are mostly extensions of its CNS activity. Very few are seen with short-term use. Side effects reported by the manufacturer at the 5 percent or higher level based on long-term studies are: headache, 19 percent (vs. 22 percent for placebo); drowsiness, 8 (vs. 5) percent; muscle aches, 6 (vs. 6) percent; nausea, 6 (vs. 6) percent; upset stomach, 5 (vs. 6) percent; and dizziness, 5 (vs. 1) percent.

The usual adult dose for Ambien is 10 mg immediately before going to bed. This should be followed by adequate fluids to assure the table clears the esophagus. The initial dose for elderly or debilitated patients is 5 mg.

The absorption of Ambien is delayed when the dose is taken with food, but the overall duration of action is not appreciably affected. Therefore, when a faster onset is desired, the manufacturer recommends that the dose not be taken with or immediately after a meal. Additional information useful in counseling patients is listed in Table 4.

MP

Patient Information for Ambien

Ambien is used to treat insomnia.

Ambien should be taken with a full glass of water just before bedtime. If it upsets your stomach, ask your doctor about taking it with a light snack.

If you experience any next day drowsiness from Ambien, do not drive a car or perform hazardous tasks. Alcoholic beverages can increase the drowsiness when you take Ambien.

It is important that you take Ambien exactly as your doctor has instructed. DO NOT increase your dose without consulting your doctor.

Ambien is generally used for up to 2 weeks. If your sleep problems continue, talk to your doctor.

Some people experience disturbed sleep for 1 or 2 days after discontinuing Ambien. This should go away in a few days. If it continues, contact your doctor.

DO NOT take any nonprescription sleep aid or hay fever medications without first asking your doctor or pharmacist.

Keep Ambien at room temperature, in its original, labeled container and out of the reach of children. In case of accidental ingestion or overdose, call your doctor or poison control center immediately. DO NOT keep or use outdated medication.

WOMEN: While taking Ambien, you should tell your doctor if you plan to become pregnant, are pregnant, or if you are breast-feeding an infant.

Most patients experience few or no problems while taking Ambien. However, be sure to tell your doctor if the following occur: Unusual thoughts or behavior, excessive confusion or excitement, excessive dizziness or drowsiness, persistent headache, blurred vision, or any other unusual, bothersome effects.

Table 4

FOR THE SYMPTOMS OF SEASONAL ALLERGIC
RHINITIS INCLUDING NASAL CONGESTION

NEW

Combining Forces for Symptom Relief

**Proven relief provided by
CLARITIN® (loratadine)
plus pseudoephedrine sulfate**

■ **Nonsedating**

The incidence of sedation with CLARITIN-D Tablets (7%) was similar to that of placebo (4%) at the recommended dose.

■ **Low incidence of nervousness (5%)**

Nervousness occurred in 5% of patients receiving CLARITIN-D Tablets at the recommended dose and in 2% of patients receiving placebo.

■ **Convenient b.i.d. (q12h) dosing**

CLARITIN-D Tablets simplify symptom relief by combining two proven ingredients into one convenient b.i.d. (q12h) tablet.

■ **No black box warning regarding
torsades de pointes type arrhythmias**

■ **Well-tolerated adverse event profile**

In controlled clinical trials using the recommended dose of CLARITIN-D Tablets (n=1023), the most commonly reported adverse events included headache (19%), insomnia (16%), dry mouth (14%), somnolence (7%), and nervousness (5%). With the exception of dry mouth and insomnia, the incidence of reported adverse events was similar to placebo.

■ **Contraindications**

Narrow-angle glaucoma, severe hypertension, monoamine oxidase inhibitor therapy, urinary retention, and severe coronary artery disease

■ **Precautions**

Use judiciously in patients with: hypertension, ischemic heart disease, hyperthyroidism, diabetes mellitus, increased intraocular pressure, prostatic hypertrophy, and in nursing mothers.

CLARITIN-D Tablets should generally be avoided in patients with hepatic insufficiency, and the dosage of CLARITIN-D Tablets should be reduced in patients with renal insufficiency.

Please see following page for brief summary of Prescribing Information.

New, b.i.d.

Claritin-D

(loratadine 5 mg and pseudoephedrine sulfate, USP 120 mg)
Extended Release Tablets

**Clear Benefits
From Start to Finish**

New, b.i.d.

Claritin-D®

(loratadine 5 mg and pseudoephedrine sulfate, USP 120 mg)

Extended Release Tablets

Clear Benefits From Start to Finish

CLARITIN-D

brand of loratadine and pseudoephedrine sulfate, USP
Long-Acting Antihistamine/Extended Release Decongestant Tablets

BRIEF SUMMARY (For full Prescribing Information, see package insert.)

CAUTION: Federal Law Prohibits Dispensing Without Prescription

INDICATIONS AND USAGE: CLARITIN-D Tablets are indicated for the relief of symptoms of seasonal allergic rhinitis. CLARITIN-D Tablets should be administered when both the antihistaminic properties of CLARITIN (loratadine) and the nasal decongestant activity of pseudoephedrine are desired (see **CLINICAL PHARMACOLOGY**).

CONTRAINDICATIONS: CLARITIN-D Tablets are contraindicated in patients who are hypersensitive to this medication or to any of its ingredients.

This product, due to its pseudoephedrine component, is contraindicated in patients with narrow-angle glaucoma or urinary retention, and in patients receiving monoamine oxidase (MAO) inhibitor therapy or within fourteen (14) days of stopping such treatment (see **Drug Interactions** section). It is also contraindicated in patients with severe hypertension, severe coronary artery disease, and in those who have shown hypersensitivity or idiosyncrasy to its components, to adrenergic agents, or to other drugs of similar chemical structures. Manifestations of patient idiosyncrasy to adrenergic agents include: insomnia, dizziness, weakness, tremor, or arrhythmias.

WARNINGS: CLARITIN-D Tablets should be used with caution in patients with hypertension, diabetes mellitus, ischemic heart disease, increased intraocular pressure, hyperthyroidism, renal impairment, or prostatic hypertrophy. Central nervous system stimulation with convulsions or cardiovascular collapse with accompanying hypertension may be produced by sympathomimetic amines.

Use in Patients Approximately 60 years and Older: The safety and efficacy of CLARITIN-D Tablets in patients greater than 60 years old have not been investigated in placebo-controlled clinical trials. The elderly are more likely to have adverse reactions to sympathomimetic amines.

PRECAUTIONS: General: Because the doses of this fixed combination product cannot be individually titrated and hepatic insufficiency results in a reduced clearance of loratadine to a much greater extent than pseudoephedrine, CLARITIN-D Tablets should generally be avoided in patients with hepatic insufficiency. Patients with renal insufficiency (GFR < 30 mL/min) should be given a lower initial dose (one tablet per day) because they have reduced clearance of loratadine and pseudoephedrine.

Information for Patients: Patients taking CLARITIN-D Tablets should receive the following information: CLARITIN-D Tablets are prescribed for the relief of symptoms of seasonal allergic rhinitis. Patients should be instructed to take CLARITIN-D Tablets only as prescribed and not to exceed the prescribed dose. Patients should also be advised against the concurrent use of CLARITIN-D Tablets with over-the-counter antihistamines and decongestants.

This product should not be used by patients who are hypersensitive to it or to any of its ingredients. Due to its pseudoephedrine component, this product should not be used by patients with narrow-angle glaucoma, urinary retention, or by patients receiving a monoamine oxidase (MAO) inhibitor or within 14 days of stopping use of an MAO inhibitor. It also should not be used by patients with severe hypertension or severe coronary artery disease.

Patients who are or may become pregnant should be told that this product should be used in pregnancy or during lactation only if the potential benefit justifies the potential risk to the fetus or nursing infant. Patients should be instructed not to break or chew the tablet.

Drug Interactions: No specific interaction studies have been conducted with CLARITIN-D Tablets. However, loratadine (10 mg once daily) has been safely coadministered with therapeutic doses of erythromycin, cimetidine, and ketocazole in controlled clinical pharmacology studies. Although increased plasma concentrations (AUC 0-24 hrs) of loratadine and/or pseudoephedrine were observed following coadministration of loratadine with each of these drugs in normal volunteers (n=24 in each study), there were no clinically relevant changes in the safety profile of loratadine, as assessed by electrocardiographic parameters, clinical laboratory tests, vital signs, and adverse events. There were no significant effects on QT, intervals, and no reports of sedation or syncope. No effects on plasma concentrations of cimetidine or ketocazole were observed. Plasma concentrations (AUC 0-24 hrs) of erythromycin decreased 15% with coadministration of loratadine relative to that observed with erythromycin alone. The clinical relevance of this difference is unknown. These above findings are summarized in the following table:

Effects on Plasma Concentrations (AUC 0-24 hrs) of Loratadine and Descarboethoxyloratadine After 10 Days of Coadministration (Loratadine 10 mg) in Normal Volunteers

| | Loratadine | Descarboethoxyloratadine |
|---------------------------|------------|--------------------------|
| Erythromycin (500 mg Q8h) | +40% | +46% |
| Cimetidine (300 mg QID) | +103% | +6% |
| Ketocazole (200 mg Q12h) | +303% | +73% |

There does not appear to be an increase in adverse events in subjects who received oral contraceptives and loratadine.

CLARITIN-D Tablets (pseudoephedrine component) are contraindicated in patients taking monoamine oxidase inhibitors and for 2 weeks after stopping use of an MAO inhibitor. The antihypertensive effects of beta-adrenergic blocking agents, methyldopa, mecamylamine, reserpine, and veratrum alkaloids may be reduced by sympathomimetic-induced increased cardiac pacemaker activity can occur when pseudoephedrine is used concomitantly with digitalis.

Drug/Laboratory Test Interactions: The *in vitro* addition of pseudoephedrine to sera containing the cardiac isoenzyme MB of serum creatine phosphokinase progressively inhibits the activity of the enzyme. The inhibition becomes complete over 6 hours.

Carcinogenesis, Mutagenesis, Impairment of Fertility: There are no animal or laboratory studies on the combination product loratadine and pseudoephedrine sulfate to evaluate carcinogenesis, mutagenesis, or impairment of fertility.

In an 18-month oncogenicity study in mice and a 2-year study in rats loratadine was administered in the diet at doses up to 40 mg/kg (mice) and 25 mg/kg (rats). In the carcinogenicity studies pharmacokinetic assessments were carried out to determine animal exposure to the drug. AUC data demonstrated that the exposure of mice given 40 mg/kg of loratadine was 3.6 (loratadine) and 18 (active metabolite) times higher than a human given 10 mg/day. Exposure of rats given 25 mg/kg of loratadine was 28 (loratadine) and 67 (active metabolite) times higher than a human given 10 mg/day. Male mice given 40 mg/kg had a significantly higher incidence of hepatocellular tumors (combined adenomas and carcinomas) than concurrent controls. In rats, a significantly higher incidence of hepatocellular tumors (combined adenomas and carcinomas) was observed in males given 10 mg/kg and males and females given 25 mg/kg. The clinical significance of these findings during long-term use of loratadine is not known.

In mutagenicity studies with loratadine alone, there was no evidence of mutagenic potential in reverse (Ames) or forward point mutation (CHO-HGPRT) assays, or in the assay for DNA damage (Rat Primary Hepatocyte Unscheduled DNA Assay) or in two assays for chromosomal aberrations (Human Peripheral Blood Lymphocyte Clastogenesis Assay and the Mouse Bone Marrow Erythrocyte Micronucleus Assay). In the Mouse Lymphoma Assay, a positive finding occurred in the nonactivated but not the activated phase of the study.

Loratadine administration produced hepatic microsomal enzyme induction in the mouse at 40 mg/kg and rat at 25 mg/kg, but not at lower doses.

Decreased fertility in male rats, shown by lower female conception rates, occurred at approximately 64 mg/kg of loratadine and was reversible with cessation of dosing. Loratadine had no effect on male or female fertility or reproduction in the rat at doses approximately 24 mg/kg.

Pregnancy Category B: There was no evidence of animal teratogenicity in reproduction studies performed on rats and rabbits with this combination at oral doses up to 150 mg/kg (885 mg/m² or 5 times the recommended daily human dosage of 250 mg or 185 mg/m²), and 120 mg/kg (1416 mg/m² or 8 times the recommended daily human dosage), respectively. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, CLARITIN-D Tablets should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known if this combination product is excreted in human milk. However, loratadine when administered alone and its metabolite descarboethoxyloratadine pass easily into breast milk and achieve concentrations that are equivalent to plasma levels, with an AUC₀₋₁₂/AUC₀₋₂₄ ratio of 1.17 and 0.85 for the parent and active metabolite, respectively. Following a single oral dose of 40 mg, a small amount of loratadine and metabolite was excreted into the breast milk (approximately 0.03% of 40 mg after 48 hours). Pseudoephedrine administered alone also distributes into breast milk of the lactating human female. Pseudoephedrine concentrations in milk are consistently higher than those in plasma. The total amount of drug in milk as judged by the area under the curve (AUC) is 2 to 3 times greater than in plasma. The fraction of a pseudoephedrine dose excreted in milk is estimated to be 0.4% to 0.7%. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. Caution should be exercised when CLARITIN-D Tablets are administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children below the age of 12 years have not been established.

ADVERSE REACTIONS: Experience from controlled and uncontrolled clinical studies involving approximately 10,000 patients who received the combination of loratadine and pseudoephedrine sulfate for a period of up to 1 month provides information on adverse reactions. The usual dose was one tablet every 12 hours for up to 28 days.

In controlled clinical trials using the recommended dose of one tablet every 12 hours, the incidence of reported adverse events was similar to those reported with placebo, with the exception of insomnia (16%) and dry mouth (14%).

REPORTED ADVERSE EVENTS WITH AN INCIDENCE OF ≥2% ON CLARITIN-D IN PLACEBO-CONTROLLED CLINICAL TRIALS

PERCENT OF PATIENTS REPORTING

| | CLARITIN-D n=1023 | Loratadine n=543 | Pseudoephedrine n=548 | Placebo n=922 |
|-------------|----------------------|---------------------|--------------------------|------------------|
| Headache | 19 | 17 | 19 | 19 |
| Insomnia | 16 | 4 | 19 | 3 |
| Dry Mouth | 14 | 4 | 9 | 3 |
| Somnolence | 7 | 8 | 5 | 4 |
| Nervousness | 5 | 3 | 7 | 2 |
| Dizziness | 4 | 1 | 5 | 2 |
| Fatigue | 4 | 6 | 3 | 3 |
| Dyspepsia | 3 | 2 | 3 | 1 |
| Nausea | 3 | 2 | 3 | 2 |
| Pharyngitis | 3 | 3 | 2 | 3 |
| Anorexia | 2 | 1 | 2 | 1 |
| Thirst | 2 | 1 | 2 | 1 |

Adverse event rates did not appear to differ significantly based on age, sex, or race, although the number of non-white subjects was relatively small.

In addition to those adverse events reported above (≥2%), the following less frequent adverse events have been reported in at least one CLARITIN-D treated patient:

Autonomic Nervous System: Abnormal lacrimation, dehydration, flushing, hypohidrosis, increased sweating, mydriasis.

Body As A Whole: Asthenia, back pain, blurred vision, chest pain, conjunctivitis, earache, ear infection, eye pain, fever, flu-like symptoms, leg cramps, lymphadenopathy, malaise, photophobia, rigors, tinnitus, viral infection, weight gain.

Cardiovascular System: Hypertension, hypotension, palpitations, peripheral edema, syncope, tachycardia, ventricular extrasystoles.

Central and Peripheral Nervous System: Dysphonia, hyperkinesia, hypertonia, migraine, paresthesia, tremor, vertigo.

Gastrointestinal System: Abdominal distention, abdominal distress, abdominal pain, altered taste, constipation, diarrhea, eructation, flatulence, gastritis, gingival bleeding, hemorrhoids, increased appetite, stomatitis, taste loss, tongue discoloration, toothache, vomiting.

Liver and Biliary System: Hepatic function abnormal.

Musculoskeletal System: Arthralgia, myalgia, torticollis.

Psychiatric: Aggressive reaction, agitation, anxiety, apathy, confusion, decreased libido, depression, emotional lability, euphoria, impaired concentration, irritability, paranoia.

Reproductive System: Dysmenorrhea, impotence, intermenstrual bleeding, vaginitis.

Respiratory System: Bronchitis, bronchospasm, chest congestion, coughing, dry throat, dyspnea, epistaxis, halitosis, nasal congestion, nasal irritation, sinusitis, sneezing, sputum increased, upper respiratory infection, wheezing.

Skin and Appendages: Acne, bacterial skin infection, dry skin, eczema, edema, epidermal necrolysis, erythema, hematoma, pruritus, rash, urticaria.

Urinary System: Dysuria, micturition frequency, nocturia, polyuria, urinary retention.

The following additional adverse events have been reported with the use of CLARITIN Tablets: alopecia, altered salivation, amnesia, anaphylaxis, angioneurotic edema, blepharospasm, breast enlargement, breast pain, dermatitis, dry hair, dry mouth, dryness, hemiparesis, hemiplegia, hepatic necrosis, hepatitis, jaundice, laryngitis, menorrhagia, nasal dryness, photosensitivity reaction, purpura, seizures, supraventricular tachyarrhythmias, and urinary discoloration.

Pseudoephedrine may cause mild CNS stimulation in hypersensitive patients. Nervousness, excitability, restlessness, dizziness, weakness, or insomnia may occur. Headache, drowsiness, tachycardia, palpitation, pressor activity, and cardiac arrhythmias have been reported. Sympathomimetic drugs have also been associated with other untoward effects, such as fear, anxiety, tenseness, tremor, hallucinations, seizures, pallor, respiratory difficulty, dysuria, and cardiovascular collapse.

OVERDOSAGE: Somnolence, tachycardia, and headache have been reported with doses of 40 to 180 mg of CLARITIN Tablets. In the event of overdose, general symptomatic and supportive measures should be instituted promptly and maintained for as long as necessary. Treatment of overdose would reasonably consist of emesis (peccary syrup), except in patients with impaired consciousness, followed by the administration of activated charcoal to absorb any remaining drug. If vomiting is unsuccessful, or contraindicated, gastric lavage should be performed with normal saline. Saline cathartics may also be of value for rapid dilution of bowel contents. Loratadine is not eliminated by hemodialysis. It is not known if loratadine is eliminated by peritoneal dialysis.

In large doses, sympathomimetics may give rise to giddiness, headache, nausea, vomiting, sweating, thirst, tachycardia, precordial pain, palpitations, difficulty in micturition, muscular weakness and tenseness, anxiety, restlessness, and insomnia. Many patients can present a toxic psychosis with delusions and hallucinations. Some may develop cardiac arrhythmias, circulatory collapse, convulsions, coma, and respiratory failure.

The oral LD₅₀ values for the mixture of the two drugs were greater than 525 and 1839 mg/kg in mice and rats, respectively. Oral LD₅₀ values for loratadine were greater than 5000 mg/kg in rats and mice. Doses of loratadine as high as 10 times the recommended daily clinical dose showed no effect in rats, mice, and monkeys.

Schering

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Interactions...

Maryland at the APhA Meeting

Over 60 Maryland pharmacists, pharmacy students and faculty traveled to Orlando, Florida in mid-March for the 142nd annual meeting and exposition of the American Pharmaceutical Association. About 25 University of Maryland students actively participated, not only in the meetings of the Academy of Students of Pharmacy, but also in the APhA meeting itself. John B. Thomas, executive committee member-at-large, chaired the ASP Publications Committee this year, which was very much involved in the redesign of *Pharmacy Today*, the APhA newspaper. Dr. Robert Beardsley chaired a joint ASP-AACP task force on professionalism that among other things wrote the new oath of the pharmacist (published in the April issue of *The Maryland Pharmacist*). Dr. Beardsley and Dr. Lynn McPherson also participated in career roundtables at the ASP meeting.

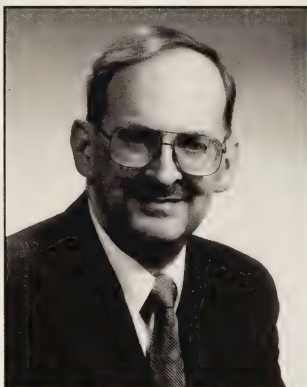
The business sessions of the annual meeting focused on changes in the process of considering policy and on substantive recommendations concerning assuring continuing pharmacist competency in contemporary practice, the professional development of students, and pharmacist working conditions. In other action, APhA affirmed the principle that any pharmacist or pharmacy that adheres to a program's quality standards and agrees to accept its compensation plan shall be able to participate in an integrated risk/capitated system or network.

The Maryland delegation was headed by David Miller and included Donald Fedder, Crystal King, Richard Baylis, Abigail Lagman, and Lynette Bradley. Dr. Francis Palumbo was busy during the meeting in his role as President of the Academy of Pharmaceutical Research and Science.

Continuing education is a major part of any professional meeting and 10 Maryland faculty were involved in sessions throughout the week. Drs. Mona Gold and Buzz Kerr offered a program on identifying and solving drug therapy problems while Drs. Magaly Rodriguez-deBittner and Rob Michocki discussed acquiring the necessary patient information to document drug therapy problems. Bob Beardsley talked about patient counseling and Lynn McPherson offered programs on diabetes education and hospice services. Poster and podium presentations were made by Drs. Hollenbeck, Fedder, McPherson and Zuckerman, as well as by Educational Advisory Committee member Paul Cuzmanes and graduate student, Ming Haw-Liu.

On the entertainment front, convention-goers

spent a wet evening at Universal Studios where Florida's spring showers made yellow rain slickers the uniform of the evening. The next evening the Maryland delegation dined in a medieval castle hosted by Henry VIII with entertainment provided by jugglers, jesters, and memorable moments by David Miller and SGA President, Scott Goldfarb.



David A. Knapp, Dean
UMAB School of Pharmacy

During the meeting, Marylander Tom Fulda was awarded honorary membership in APhA for his work on behalf of pharmacists in connection with the implementation of OBRA 90. Mr. Fulda was a longtime employee of the Health Care Financing Administration until he recently took a position heading drug use review activities at the USP. The convention concluded with the installation of President-Elect Calvin Knowlton, who earned his Ph.D. in pharmacy administration at the University of Maryland.

MP

The theme for MPhA's 113th Annual Convention is **A New Frontier for Pharmacy**, a reflection of the many exciting opportunities for pharmacists. MPhA has planned a challenging series of continuing education programs focusing on the challenges facing pharmacists. In addition, we provided for lots of time to relax and enjoy the beach at Maryland's premiere resort.

This year, MPhA convention attendees can earn more than 10 continuing education credits towards their relicensure requirements. Our business meetings have been streamlined to give everyone a chance to participate in the Association's activities.

If you've never attended a MPhA Convention, this is the year to give us a try.

Convention Events

Sunday, June 18, 1995

11:00 - 3:00 Golf Tournament

1:00 - 5:00 pm Registration

2:00 - 4:00 pm Welcoming Reception

9:00 - Midnite Western Hoe-Down

Kick off the start of our Convention with country line-dancing and desserts that'll help "rope you in" to the pioneer spirit of this year's Annual Meeting.
Sponsored by FoxMeyer

Monday, June 19, 1995

7:30 - 8:30 Bagel Breakfast

8:30 - 10:30 **Pharmaceutical Care -- The Changing Responsibilities of Today's Pharmacists**
Sponsored by Glaxo

10:00 - Noon Spouses Brunch and Fashion Show

10:30 - 12:30 MPhA House of Delegates
First Business Session

12:30 - 2:30 Trade Exposition and Luncheon
Lunch Sponsored by Marion Merrell Dow

2:30 - 4:30 pm **The Voice of Pharmacy Town Meeting**
Quality of Life Issues
Sponsored by Schein

6:30 - 10:00 Annual Crab and Chicken Feast
at Berlin Fire Hall



Tuesday, June 20, 1995

7:00 - 8:00 Continental Breakfast

8:00 - 10:00 **Current Trends in the Treatment of Hyperlipidemia**
Sponsored by Upjohn

10:00 - 11:30 SAMPA Brunch and Business Session

10:00 - 12:30 MPhA House of Delegates
Second Business Session

12:30 - 2:30 MPhA Trade Exposition and Luncheon

2:30 - 4:00 **Counseling Patients with Diabetes**
Sponsored by Becton Dickinson

6:00 - 7:00 Banquet Cocktail Reception
Sponsored by McKesson

7:00 - 9:00 Annual Awards Banquet

9:00 - 11:00 Desserts Galore Reception
Sponsored by AmeriSource

ists Association • June 18-21 1995
A New Frontier
for Pharmacy
Convention • June 18-21 1995

Wednesday, June 21, 1995

8:00 - 9:00 Bagel Breakfast

9:00 - 12:00 **Getting Paid for Cognitive Services -- The First Steps**

12:30 - 2:00 Student Career Luncheon



Accommodations

Once again, the Maryland Pharmacists Association has been able to obtain for attendees discounted hotel rates for one of Ocean City's finest resort hotels.

In previous years, the hotel sold out of reserved rooms at the special MPhA convention rate. Don't be disappointed! Complete the enclosed reservation request form and mail it directly to the Sheraton Ocean City Resort. All room reservations must be received by the hotel no later than June 1, 1995. Neither MPhA nor the Sheraton can guarantee space availability at these rates after the deadline.

To reserve your room, call the Sheraton Ocean City Resort Hotel at (800) 638-2100.



Room Rates

Rates are subject to 8 percent room tax. One night deposit is required to guarantee your reservation. Children under 17 stay free of charge in same room as parents. Rooms are available for check-in at 3:00 pm. The Sheraton Ocean City Resort accepts personal checks for deposit only. A 72-hour cancellation or change notice is required.

Guest Rooms (per night)

| | |
|---------------------|-------|
| Single/Double | \$125 |
| Triple | \$139 |
| Quad | \$153 |
| Cabana Suites | \$250 |
| Studio Suites | \$190 |

Condominiums (per week)

| | |
|----------------------------|---------|
| With Maid Service | \$1,150 |
| Without Maid Service | \$ 950 |

Registration

To register for the Annual Convention of the Maryland Pharmacists Association, complete the registration form that appears on page 16 of this issue of *The Maryland Pharmacist*. Please print or type clearly. Return the form, with your check or money order for the total convention registration to the address listed at the bottom of the form.

Admission to all functions will be by ticket or badge. Pick up badges and other registration materials at the MPhA Registration Desk beginning Sunday, June 18 at 1:00 pm or on Monday, June 19 beginning at 7:30 am. You must register with the MPhA Convention to take advantage of special convention hotel rates. Spouses must register or purchase function tickets to attend any special activities.



A New Frontier for Pharmacy

Maryland Pharmacists Association ■ 113th Annual Convention
Sheraton Ocean City Resort Hotel ■ June 18-21, 1995

Registration

To register for the 113th Annual Convention of the Maryland Pharmacists Association, complete this registration form. Please print or type clearly.

You must register with the MPhA Convention to take advantage of special convention hotel rates. Spouses, guests and children must register or purchase function tickets to attend *any* convention events.

Full Registration includes admission to all meetings, social events, and processing of continuing education credits. Spouse/Guest Registration includes admission to all social events, plus the annual SAMPFA Fashion Show and Brunch. Single Day registration includes processing of continuing education credits for that day only. Tickets to social events for Single Day Registrants must be purchased separately. Children must also be formally registered to enter the Trade Exposition or other social events. The Child Registration fee does not include the Crab Feast or Banquet.

Questions?

Call 800-833-7587
or 410-727-0746

MPhA

650 West Lombard St.
Baltimore, MD 21201

Attendee Information

Name _____

Pharmacy/Company Name _____

Mailing Address _____

City/State/Zip _____

Telephone _____

Spouse/Guest Name(s) _____

Children Name(s) _____

Registration Fees

Please check the appropriate box(s).

| Full Registration | Before June 1 | After June 1 |
|-------------------|---------------------------------|---------------------------------|
| MPhA Member | <input type="checkbox"/> \$ 130 | <input type="checkbox"/> \$ 150 |
| Spouse/Guest | <input type="checkbox"/> \$ 110 | <input type="checkbox"/> \$ 130 |
| Non-Member | <input type="checkbox"/> \$ 170 | <input type="checkbox"/> \$ 190 |
| Child Under 18 | <input type="checkbox"/> \$ 10 | <input type="checkbox"/> \$ 20 |
| Pharmacy Student | <input type="checkbox"/> \$ 10 | <input type="checkbox"/> \$ 20 |

Daily Registration

| | | |
|------------|--------------------------------|--------------------------------|
| Single Day | <input type="checkbox"/> \$ 30 | <input type="checkbox"/> \$ 40 |
|------------|--------------------------------|--------------------------------|

Day Attending _____

Extra Event Tickets

Crab & Chicken Feast

| | | |
|----------------|--------------------------------|--------------------------------|
| Adult/Students | <input type="checkbox"/> \$ 35 | <input type="checkbox"/> \$ 40 |
| Child Under 12 | <input type="checkbox"/> \$ 15 | <input type="checkbox"/> \$ 15 |

MPhA Annual Banquet

| | | |
|----------------|--------------------------------|--------------------------------|
| Adult/Students | <input type="checkbox"/> \$ 25 | <input type="checkbox"/> \$ 30 |
| Child Under 12 | <input type="checkbox"/> \$ 15 | <input type="checkbox"/> \$ 20 |

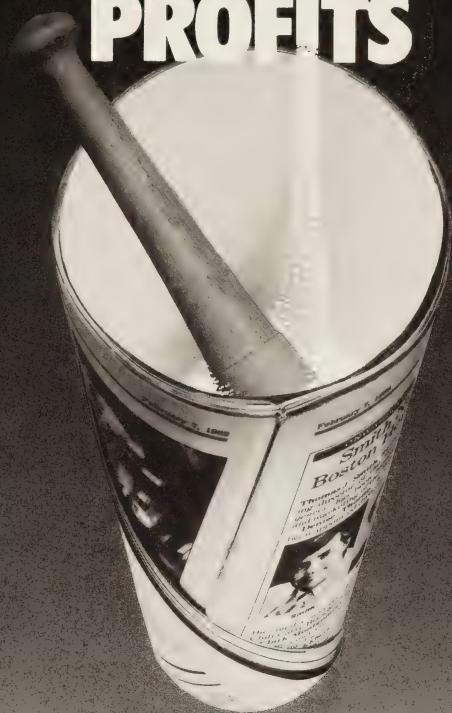
Spouse Events

| | | |
|---------------------|--------------------------------|-------------------------------|
| Fashion Show/Brunch | <input type="checkbox"/> \$ 15 | <input type="checkbox"/> \$20 |
| Business/Brunch | <input type="checkbox"/> \$ 10 | <input type="checkbox"/> \$15 |

Grand Total

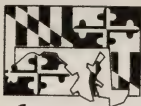
Do you wish to serve as an MPhA delegate at the business sessions? ☐ Yes ☐ No

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Good Records Are For Listening

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Melvin Rubin, P.D., Secretary and Commissioner

The Board of Pharmacy receives information from many sources which allege infractions of pharmacy laws. Recently we have had a number of communications which resulted from investigations of physician prescribing habits.

When a physician is investigated for these actions, pharmacies in the area may be canvassed and asked to provide printouts of prescription records for that physician or perhaps for specific patients. This may be compared to the doctor's records to determine if the prescriptions were written in good faith.

Sometimes these records, which are forwarded to the Board of Pharmacy to review for appropriate dispensing habits, have shown pharmacists to be dispensing controlled dangerous substances (CDS) in amounts which suggest possible abuse. The Board then is compelled to investigate the pharmacy.

Sometimes the records will show quantities dispensed as being much more than the Food and Drug Administration's approved adult dose. At other times we have seen multiple CDS

items prescribed which may individually have been within dosing guidelines, but collectively show dangerous quantities of narcotics or other controlled substances.

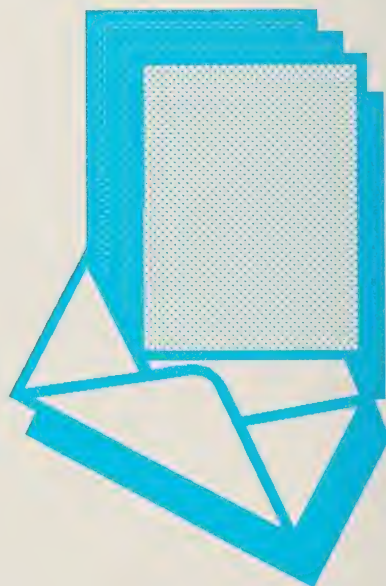
Since the law places a corresponding responsibility on the pharmacist to assure that controlled dangerous substances are dispensed for medical need in appropriate quantities, the pharmacist cannot assume that any dose is correct just because it was written by a physician.

Don't misinterpret this to mean that you cannot *ever* fill a prescription for a quantity or dosage larger than the norm. Unusual doses *may* be correct but the pharmacist has to be satisfied that it is appropriate on a case-by-case basis.

Prescriptions for terminal cancer patients, particularly in hospice situations are certainly evaluated differently than prescriptions for appetite control medications.

For example, when the Board sees that 200 mg of alprazolam is dispensed every week, red flags go up. An investigation would focus on supporting data to indicate appropriateness. Notations in the computer or on the back of the prescription indicating how you determined that the prescription was one you should dispense are a good way to document that you used good faith in dispensing a questionable prescription.

It's common sense that in questionable cases the pharmacist should document that they spoke to the prescriber, not the nurse or secretary. Sometimes you have to insist that they put you through to the prescriber, but you certainly are on more solid ground getting the information straight from the responsible person than by risking the problem of a third-party incorrectly interpreting an order.



Computer systems now give warnings on over utilization. Some new enhancements tell you if the dose prescribed is higher (or lower) than the normal range.

At the same time that this increases your ability to determine appropriate usage, it increases your responsibility to do just that. You have less excuse for dispensing larger than normal quantities without verification when you can readily see that is the case.

Does that mean you would be better off not having drug utilization enhancements on your computer? In my opinion, the pharmacist who chooses not to use modern technology as the modules become standards of practice faces *more* legal problems for not even attempting to reach that attainable standard than does the pharmacist who has the capability but makes a mistake in judgement.

Put another way, if you choose to bury your head in the ground to avoid responsibility, you may have trouble getting your head out in time to breathe.

Pharmacists are not required to fill prescriptions which, in their professional judgement, are not appropriate or dangerous to the patient. Here, also, is a danger of being too conservative and possibly harming a patient. You cannot automatically say that a prescription should not be filled just because the dosage is double the norm. You have to be able to substantiate that an informed decision was made in each case and that you have verified such.

The worst trap to fall into is denying a prescription because of the appearance of a person. Being well dressed, poorly dressed, being of one race or another, or being young or old does not give you any indication whether a person should be served or not.

Using appearance of the person as a criteria puts you at risk of violating more than just pharmacy laws. Discrimination laws apply also. When in doubt, verify the prescription!

Does this all mean that the pharmacist is in an impossible position -- damned if you do, damned if you don't? No. It just means that you have to meet your professional responsibility to determine if a prescription is proper. A reasonable effort to assure that the medication and dose is correct will probably keep you out of trouble. If your files are full of borderline prescriptions, you had better have more justification than if you only have a few occasions when tough decisions had to be made. Refusing a prescription for 200 mg of alprazolam a week without being able to obtain supporting documentation would probably not be a tough decision.

One other point. It's better to err slightly on the side of the patient when necessary. If it is a weekend and you can not get all the confirmation you need when you suspect potential abuse, advance enough medication to see the patient though until you can reach the doctor or any authorities you need. You might get "burned" for some doses, but the Board and other authorities will take into account your attempt to practice in good faith.

MP



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Litigation Update

Are You a Health Care Provider?

David B. Brushwood, R.Ph., J.D.

The Superior Court of Connecticut has recently ruled that pharmacists are not always to be considered "health care providers" for the purposes of malpractice lawsuits.

The case giving rise to this ruling involved the allegedly mistaken dispensing of Cefitin to a patient who presented a prescription for Cipro. The patient claims to have become very ill as the result of receiving Cefitin by mistake. He alleged that his injuries were caused by the pharmacists' negligence and carelessness.



David Brushwood

The pharmacist filed a motion to dismiss on the grounds that the patient had not attached to his complaint a certificate alleging that the pharmacist's conduct had breached the prevailing standards of care. In many states, malpractice reform has led to requirements that lawsuits alleging professional malpractice by a health care provider be accompanied by evidence that the patient has first confirmed that the defendant violated a professional standard.

The court reviewed a previous reported case from Connecticut in which another court had determined that the pharmacist's duty to warn patients requires professional expertise to evaluate, thus a pharmacist is a "health care provider" in a case alleging the failure of a duty to warn. The Superior Court did not disagree with that ruling.

After examining the results of cases from other jurisdictions, and the language of the applicable Connecticut statute, the court concluded that a pharmacist can rationally be included as a "health care provider." However, in this case the patient had alleged that the pharmacist had breached a duty of ordinary care, not a professional standard of care. Thus, when the allegation is that the pharmacist simply dispensed the wrong drug, as distinct from an allegation that a pharmacist failed in a cognitive service, the requirements relating to "health care providers" do not apply. The pharmacist's motion was denied.

MP

Based on: *Shaw v. Caldor*, 1995 Conn.Super.Lexis 567 (February 23, 1995). Copyright 1995, David B. Brushwood. All rights reserved. Reprinted from *Dickinson's Pharmacy*, April, 1995.

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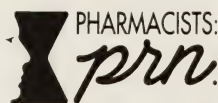
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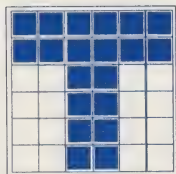


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At Issue

Should Pharmacists Prescribe?

*Carolyn Jones, Pharmacy Student
University of Maryland School of Pharmacy*



he role of the pharmacist has shifted over the past few decades. For centuries, the

pharmacists' "...office is only to be the physician's cook"¹.

Communication between the patient and pharmacist was discouraged. With changes in the health care system, pharmacists are urged to expand their traditional role. Drug oriented therapy has become patient centered recovery.

Communication between the health professional and the patient is necessary for proper treatment and recovery to be achieved. The growing crisis in the United States has created a need to increase access to health care services while containing costs. This crisis can be solved, in part, by non-physician health care personnel². The pharmacist has the most extensive training in pharmacology. It makes sense that prescribing and managing drug therapy eventually describe the role of pharmacists.

Pilot projects in California and legislation in Florida have recognized the need to expand the duties required of pharmacists. In California, certified pharmacists provided complete care of ambulatory patients with chronic diseases; this includes geriatric patients in extended care facilities, psychiatric patients, and selected inpatients³. They met with the physician every other week to review the treatment prescribed. Results of this project showed that there was no difference between the therapy provided by physicians and that given by pharmacists. In many cases, the patient reacted more positively to the pharmacist than to the physician. In Florida, public pressure for more inexpensive ways of providing health care resulted in the Pharmacy Self Care Consultant Law in 1986. The purpose of this law is "to provide the consumer with access to effective medications at relatively lower cost and less inconvenience than is involved in seeing a physician for minor self-limiting medical conditions"⁴.

The evolving health care system has required pharmacists to play a more central role in primary health care. A pharmacist's primary role is to provide pharmaceutical care services, which have been defined by the APhA⁵ as:

- participating in the drug therapy decision process and selecting therapeutic objectives;
- selecting the drug product dosage form;
- selecting the drug product source supply;
- participating in the determination of the dose and dosage schedule;
- preparing the drug product for patient use;
- providing the drug product to the patient;
- providing drug information to patient and other health care providers;
- monitoring the patient to maximize compliance;
- monitoring the patient to detect adverse drug reactions and interactions; and
- monitoring the patient to enhance the probability that therapy proceeds in accord with therapeutic objectives.

Also, pharmacists also frequently detect undiagnosed conditions and refer the patient to a physician.

The services provided by pharmaceutical care would not need to expand far to include prescribing of medication. Many clinical pharmacists already participate in the determination of the drug product and dose, but there are many barriers left to overcome before they are sole prescribers of medicine. The main obstacle is the refusal of other health care professionals to

relinquish their patient care functions. Other barriers may include the need for further education, and availability of resources "such as supportive personnel, space, and documentation systems, and compensation."⁵ Pharmacists content in their traditional roles may resist the change due to added responsibilities and the pressures of liability.

These barriers can be overcome if the benefits can outweigh the negative aspects of this proposal. Improper drug use is associated with adverse drug reactions and hospitalizations. A study disclosed a 21 percent prescription-writing error rate among family practice residents.⁶ Approximately four percent of the prescriptions filled contain problems that are detected by pharmacists. Prescribing and drug use problems, such as inappropriate drug, directions, quantities, or authorized refills, may be diminished by allowing pharmacists to prescribe the medication.

Pharmacists also keep up-to-date on drug research and development of improved medications or creation of a higher quality replacement, resulting in higher quality health care. A pilot study of capitation reimbursement in the Iowa Medicaid program, pharmacists were found to perform activities to control drug costs.⁶ A similar incentive would exist where pharmacists would be the implementer of health care. The results could include increased generic substitution, increased number of days supply dispensed, increased use of lower cost drugs in a few therapeutic categories, and slightly increased switching

from prescription to over-the-counter drugs. These changes all signify reduced patient health care costs.

Health care reforms have brought many changes to the manner in which patients are treated. Many professionals are redefining their roles in terms of the benefits given to the patients. Pharmacy is still expanding greatly to accommodate these changes and the changes to come.

The role of a pharmacist as a prescriber will benefit the patients by providing them with a higher quality of care, greater practitioner accessibility, and reduced prescription costs. This is the future of pharmacy, as William Zellmer states in the American Journal for Hospital Pharmacists⁷, "Prescribing medications, a corollary function that derives naturally from expertise in drug therapy, is within the destiny of pharmacy." **MP**

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Should Pharmacy Students Work?

A Survey of Pharmacist Opinions

Educational Advisory Committee
UMAB School of Pharmacy



There are many reasons why students work during pharmacy school. Maybe it's because of financial need. Sometimes it's because the student wants to take advantage of the learning opportunities that exist in pharmacy practice settings. However, if a student's employment is poorly managed or excessive, it could impact negatively on academic performance.

The Educational Advisory Committee of the School of Pharmacy, comprised of pharmacists from all areas of practice, have made the issue of working pharmacy students a priority. Many members of this committee employ pharmacy students. The goal is to identify ways which employers and the School can work together to benefit students by striking a better balance between outside employment and academics.

*This survey is voluntary and anonymous. Please return the completed questionnaire **by May 30, 1995** to: Gary Hollenbeck, University of Maryland, School of Pharmacy, 20 North Pine Street, Baltimore, Maryland 21201.*

MP

In completing this survey, please check the most appropriate answer. In some instances, your written thoughts are requested.

1. ☐ I do employ pharmacy students.
☐ I do not employ pharmacy students.
2. The student(s) I employ is/are:
☐ Bachelors Year 3
☐ Pharm.D. Year 1
☐ Pharm.D. Year 2
☐ Pharm.D. Year 3
☐ Pharm.D. Year 4
☐ Graduate Student
3. The average number of hours my student employees work is _____.
4. ☐ I would like students to work more hours a week while in school.
☐ I would not like students to work more hours a week while in school.
5. I estimate that the average annual financial aid (eg., loans, grants, scholarships) available to the student(s) I employ is approximately:
☐ No Financial Aid
☐ up to \$ 4,000
☐ \$ 4,001 to \$ 8,000
☐ \$ 8,001 to \$12,000
☐ \$12,001 to \$16,000
☐ More than \$16,000

6. My primary place of practice is:

- ☐ Chain pharmacy
- ☐ Independent Pharmacy
- ☐ Hospital Pharmacy
- ☐ Long Term Care Pharmacy
- ☐ Infusion Pharmacy
- ☐ Other Pharmacy Practice
- ☐ Job Not Related to Pharmacy

7. The School of Pharmacy should provide an academic schedule that permits a reasonable opportunity for outside employment.

- ☐ Strongly Agree
- ☐ Agree
- ☐ No Opinion
- ☐ Disagree
- ☐ Strongly Disagree

8. As an employer of students, I need to be flexible when it comes to scheduling work to accommodate the students' academic needs.

- ☐ Strongly Agree
- ☐ Agree
- ☐ No Opinion
- ☐ Disagree
- ☐ Strongly Disagree

9. I adjust a student employee's work schedule because of the demands of their academic program.

- ☐ Never
- ☐ Sometimes
- ☐ Frequently

10. I do/do not employ pharmacy students because....

11. In my opinion, students work because....

12. What effect do you think outside employment has on study time and habits?

13. What steps could or should be taken by the School, students and/or employers relating to the issue of student work?

14. What shifts (times of day) do your student employees currently work?

Monday

Tuesday

Wednesday

Thursday

Friday

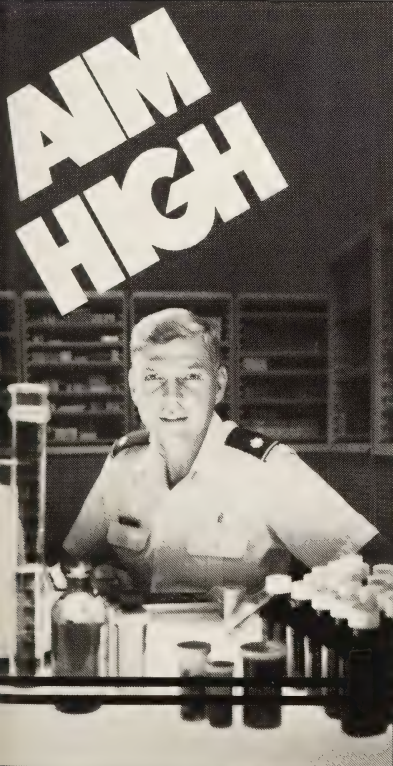
Saturday

Sunday

Remember, please return your survey by
May 30, 1995!

Supporting Student Activities

MPhA President Arnold Davidov presents a \$1,000 check to Academy of Students of Pharmacy President Scott Goldfarb. MPhA annually provides money to the students to support their attendance at professional meetings, involvement in community service projects and much more.



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Maryland Pharmacists

The Entrepreneurs

This Month

*Chris Brown, Pharmacist
Schindel's Pharmacy, Hagerstown, Maryland*



banana split, no cherries, please", said the young woman at the counter. Chris

Brown didn't hear her. The year was 1969, and he was watching the pharmacist behind the prescription counter.



Chris was fascinated with all aspects of Schindel's Pharmacy. He was not only the soda clerk, but also handled the deliveries for the pharmacy. When delivering an important medication or health care supply, Chris loved how appreciated the customer made him feel. He would knock on the door and be greeted by a

warm friendly smile. His customers always thanked him and let him know how much Schindel's service meant to them. When making deliveries, he felt truly needed, and that made him feel good.

While serving chocolate malts, cherry cokes, and ice cream sundaes was not as rewarding as his delivery work, at least when he worked the soda fountain he could watch the pharmacist. Chris was impressed with the satisfaction Schindel's pharmacist seemed to receive from his job. The pharmacist confidently dispensed important medications and good advice. He could turn a worried mother's frown into a smile with a vial of medication and some of his warmly worded wisdom. Everyone left the pharmacy just a little happier than when they arrived. Thinking about this, Chris remembered his banana split customer, and apologizing while he worked, created a calorie laden delight for the young woman.

Chris worked hard at Hagerstown High School. When he graduated in 1970, he knew the medical field was the place for him. He briefly considered medical school, but remembering his warm experiences at Schindel's Pharmacy, he enrolled at West Virginia University. Chris graduated in 1975 with a B.S. degree in pharmacy. While at the college, he had served as a pharmacy intern with then owner of Schindel's, Cy Jones.

While serving his internship at Schindel's, Dr. Jones had mentioned to Chris that he was considering retirement. Chris had dreamed of one day owning this store. In 1982, Chris Brown's dream became a reality. He bought Schindel's Pharmacy.

Chris and his wife Debbie modernized some aspects of the pharmacy, while keeping the "old fashioned" appearance as much as possible. They put in a drop ceiling, greatly improving the lighting. The pharmacy was computerized in 1988. Other improvements included a public fax service, a package mailing center, and an extensive selection of greeting cards and wrapping paper. Even with its new improvements, the pharmacy still retained its "Old Town" feel.

Schindel's Pharmacy was opened in 1897 on "Doctor's Row". In 1926 Mr. Schindel purchased a site two blocks away and moved the pharmacy to its current home. Schindel's Pharmacy operates in Hagerstown, a town of about 58,000 people.

Although there are also 34 other pharmacies in the Washington County area (including three other independent pharmacies), Chris Brown's store still occupies a special place in the hearts of its residents. Almost 100 years after the pharmacy opened, people still enjoy coming into the pharmacy for good advice, medications, and a great ice cream sundae. **MP**



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Continuing Education Quiz

May 1995 -- Schizophrenia/Insomnia

This month's questions are taken from the article on recently introduced drug therapies for insomnia and schizophrenia that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. There is **no charge** for this quiz for MPhA members (non-members \$5.00). The completed quiz for this issue must be received by October 31, 1995. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name _____

Address _____

City/State/ZIP Code _____

1. Risperidone has a reported advantage over clozapine in that risperidone causes less of which of the following adverse drug reactions?
 - a. Agranulocytosis
 - b. Birth defects
 - c. Extrapyramidal symptoms
 - d. Hepatotoxicity
2. When considering the concept of how the thought process works and what causes mental disorders as they relate to neurotransmitters, of the following, the most important concept is:
 - a. balance
 - b. ionization
 - c. polarization
 - d. valance
3. The psychotic symptoms of patients suffering from schizophrenia include all of the following *except*:
 - a. delusions
 - b. hallucinations
 - c. melancholy
 - d. suspiciousness
4. Risperidone exerts its greatest activity on which of the following sets of physiologic receptor sites?
 - a. Alpha-2 and beta-2
 - b. Beta-2 and 5-HT₂
 - c. Alpha-2 and dopamine-2
 - d. Dopamine-2 and 5-HT₂
5. Risperidone exerts which of the following actions on the receptor sites referred to in question #4?
 - a. Blockade
 - b. Stimulation
6. Risperidone has a reported advantage over haloperidol and the phenothiazine derivatives, in that risperidone causes less of which of the following adverse drug reactions?
 - a. Agranulocytosis
 - b. Birth defects
 - c. Extrapyramidal symptoms
 - d. Hepatotoxicity
7. The most important neurotransmitter in relation to sleep and the action of hypnotic drugs is:
 - a. acetylcholine
 - b. dopamine
 - c. gamma-aminobutyric acid
 - d. serotonin
8. The neurotransmitter referred to in question #7 reduces CNS neuronal activity and allows for sleep by enhancing the entry of which of the following ions into neurons?
 - a. Bicarbonate
 - b. Chloride
 - c. Potassium
 - d. Sodium
9. Zolpidem exerts its greatest activity on which of the following physiologic receptor sites?
 - a. Alpha
 - b. Beta
 - c. Delta
 - d. Omega

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Rx LICENSE TAGS are still available! A special benefit "for members only" that costs only a nominal fee. If interested, call Mary Ann at the MPhA offices toll-free, (800) 833-7587.

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Placing an Ad

Have something to sell, rent, or trade? Need a pharmacist? Looking for a new position? MPhA members can place a classified ad in *The Maryland Pharmacist* for free. MPhA will remove member ads after six months unless otherwise notified by the member. Non-members may also place a classified ad. The ad placement charge is \$10 for a maximum of 50 words plus 50 cents per word greater than 50. To place an ad, call MPhA at (800) 833-7587.

Next Month:

A complete overview of the 1995 Legislative Session.

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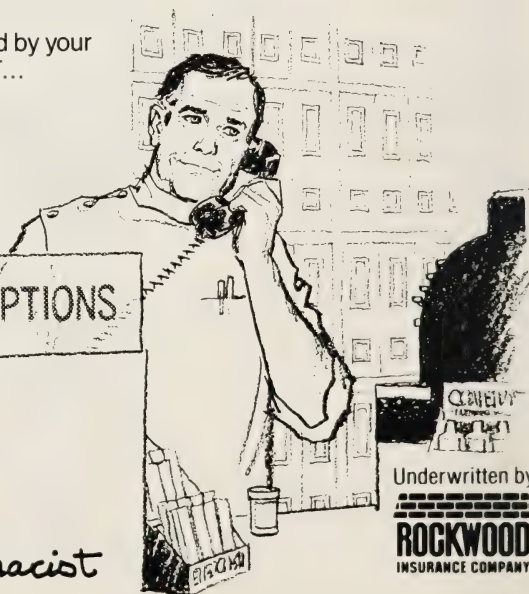
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NEWSLETTER

The Maryland Pharmacists Association

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It's Approved

No, it's not a new drug! It's just one more member benefit from MPhA. Beginning in July, the monthly continuing education articles appearing in *The Maryland Pharmacist* will now be ACPE-approved through the Maryland Continuing Education Coordinating Council. That means that any credits you earn through our publication will be automatically accepted by any other state Board of Pharmacy that recognizes ACPE programs.

Remember, these one-credit hour programs are *free* to all MPhA members (non-members pay \$5.00).

Welcome New Members

A special "hello" goes out to the latest members to join MPhA:

| | |
|--------------------|---------------------|
| Femi Ajayi | Arnold "Skip" Amass |
| Michele Bonistalli | Stephen Davis |
| W. Robert Elliott | Michelle Marks |
| Edwin Morgan | Mary Ogunwuyi |
| Godfrey Ukwuoma | Leila Valencia |
| Mary I. Ventura | William Wier |
| Norman Yockelson | |

7 Out of 100

Seven Marylanders were selected by *Drug Store News* for their top 100 most influential pharmacists in America. They are: **Stanton Ades, Leonard DeMino, Rebecca Finley, Robert Kerr, David Knapp, Jim Miller, and Ellen Yankellow.**

June 1995

The MPhA Newsletter is published monthly except during the months of July and August when the issues are combined. For information about any article contained herein, contact MPhA at (410) 727-0746 or toll-free at (800) 833-7587. President: Arnold Davidov, P.D.; Chairman, ● Board of Trustees: Howard Schiff, P.D.; Production Manager: David Miller, P.D..

License Renewal Fees to Increase

After escaping the first round of collections, pharmacists now join other health professionals in paying "Practitioner Assessments" for the Health Care Cost and Access Commission. Beginning with 1995 biennial renewals, the Board of Pharmacy will collect an additional \$64.00 fee on top of the current license renewal fee.

The Maryland General Assembly established the Health Care Access and Cost Commission (HCACC) in 1993 to develop and carry out new health care policies including: designing a comprehensive standard health benefit plan, developing a database on all non-hospital health care services, and developing a payment system for all health care practitioner services.

Funding for the HCACC comes for health care practitioners and payers. Assessments on health care practitioners cover one-third of HCACC's budget; payers fund the remaining two-thirds.

Thanks to MPhA's efforts, pharmacists statewide had a little extra in their pocket last year. All other health care practitioners began paying the HCACC assessment in 1994.



HCFA 1115 Waiver

If all goes according to plan, the State of Maryland and the Department of Health and Mental Hygiene (DHMH) will be pursuing a HCFA 1115 waiver to permit experimentation with the Medical Assistance Program. Federal Medicaid regulations and statutes currently restrict states to providing medical services to eligible recipients in certain, specific ways.

An 1115 Waiver, a reference to the section in the Social Security Code which permits states to obtain release from some of those regulations, is a formal application to the Health Care Finance Administration which details exactly what Maryland proposes to do to provide the same or better level of service to recipients while reducing costs to both the State and the Federal government.

MPhA President **Arnold Davidov** has been appointed by DHMH Secretary Martin Wasserman to represent pharmacy on a Waiver Planning Committee. He will be directly involved in presenting pharmacy's views on what has worked for Medicaid -- the on-line claims adjudication and DUR programs -- and how pharmacy has helped reduced costs by managing care.

MPhA has convened a multi-practice Task Force to follow the waiver application process. The Task Force includes representatives from Rite Aid, Giant, Safeway, EPIC, Care, long-term care, and other major forces in Maryland pharmacy. More information about the HCFA Waiver process will be forthcoming from MPhA.

Newly Certified Pharmacists

The Board of Pharmaceutical Specialties (BPS) has granted board certification in nuclear pharmacy to 54 pharmacists and in nutrition support to 73 pharmacists. Among those Maryland pharmacists who recently completed the rigorous certification process are **Karl Gumpfer** of Columbia (nutrition support) and **Jasper Watkins, III**, of Silver Spring (nuclear pharmacy).

BPS was founded in 1976 to formally recognize specialty areas within pharmacy. In addition to nuclear and nutrition support, BPS also certifies pharmacists in pharmacotherapy and psychiatric pharmacy practice. BPS recently appointed two Marylanders to the councils that govern the certification process of each specialty. These pharmacists are **Lisa Lifshin** of Chevy Chase and **Duann Vanderslice** of Baltimore.



Bill Protects Compounding

Congressman Bill Brewster (D-OK) has introduced House Resolution 598, entitled the "Pharmacy Compounding Preservation Act of 1994." Brewster, the only pharmacist currently serving in Congress, introduced this legislation at the request of national pharmacy organizations to clarify that the art and science of compounding is one that is unique to pharmacy. Recent actions by the Food and Drug Administration claim that the use of bulk products and compounding is essentially drug manufacturing and is therefore subject to the FDA's regulation.

More than 70 Congressmen have shown their support by adding their names to the sponsorship of HR 598. This includes Maryland Congressman Roscoe Bartlett of the First Congressional District. The bill has been referred to the Committee on Commerce; at present, no hearing on the legislation has been scheduled.

It's A Good Thing

Have you seen the latest trend in product ordering? Many distributors will now take major credit cards for purchases. But who in their right mind would use a credit card to purchase inventory? Those who want to take cheap vacations, that's who!

Several MPhA members report that they have obtained an "affinity" credit card with a major airline. Then, for each dollar they charge -- inventory and supplies included -- they earn frequent flyer miles. And, since payment is generally due in 30 days instead of 14 days, there is an additional advantage to this "charge it" philosophy.

Upcoming Health Events

Telephone numbers are provided for additional information and promotional materials.

July

National Eye Exam Month (708) 843-2020

September

Cholesterol Education Month . . . (301) 251-1222

Pediculosis Prevention Month . . . (800) 446-4672

Sickle Cell Month (800) 421-8453

PDN Sold

One year ago, this Newsletter reported on the formation of a unique "pharmacy owned" benefit management company -- Pharmacy Direct Network (PDN). A major undertaking of the National Association of Chain Drug Stores, with assistance from NARD, PDN began soliciting pharmacy membership for an initial investment of \$300.

On May 16 of this year, PDN was bought by American Stores Company, a national drug chain. While complete details are being mailed in proxy materials to member stores this month, the key points of the sale are:

- American Stores will acquire the PDN network, which will continue to provide pharmacy benefit management services;
- PDN will continue to service its existing benefit contracts;
- Current PDN members will receive financial incentives from American Stores for continued participation as a provider in the network;
- Under the new arrangement, no community pharmacy will be "locked out" of the network.

NARD Updates Claim Form

NARD has released a new version of its Pharmacist Care Claim Form, the first commercially available pharmacy services documentation form.

The revision features the incorporation of the National Council for Prescription Drug Programs (NCPDP) professional pharmacy service codes. In addition to the NCPDP codes, the new version also includes a "level of service" field which allows pharmacists to indicate the degree of time, effort, intensity, and/or resources involved in rendering a patient service.

The NARD Pharmacist Care Claim Form is available in both hand-written and pin-fed computer generated versions. They are available from MedPass by calling (800) 438-8884.

New!

APhA President Resigns

Citing conflicts between his role as the elected president of the largest national pharmacist organization and his responsibility as president of OmNex, a Fox-Meyer subsidiary, APhA President Bob Davis announced his resignation on May 25.

In making the difficult decision, Davis put his profession first when he stated "when the profession is facing significant threats and challenges.... I cannot have APhA's and my employer's intentions questioned because of the nature of their businesses and my leadership position." Current APhA President-Elect Calvin Knowlton has assumed the position of President.

Criminal Background Checks

Under pressure from legislative auditors, the Maryland State Board of Pharmacy and other health occupations licensing agencies are moving closer to conducting regular criminal background checks on all new and current license and permit applicants.

According to the auditors, criminal background checks through cross-matching of names and social security numbers with the Department of Public Safety and Corrections should aid the Board's in identifying any licensee or permit holder who may have violated part of the professional statutes.

The Board is reviewing how the estimated \$18 per person charge will impact on license and permit fees. MPhA leadership is monitoring this issue to ensure that the rights of individual pharmacists are not jeopardized.



Third-Party News

PCS

In an attempt to increase pharmacists involvement in public health initiatives, PCS has added a new message to its prospective drug utilization review program. For female patients of a certain age, a reminder to schedule a mammogram will be transmitted to the pharmacist.

Blue Cross/Blue Shield

Think you have a patient that is defrauding BCBS of Maryland? If so, contact Pat Haak at their Fraud and Abuse Special Investigation Unit. Pat's hotline is (410) 998-5480 or toll free (800) 336-4522.

Blue Cross has also issued new pharmacy provider contracts for all of its HMO and insurance prescription benefit business. If you have not yet received your contract, contact Advance/Paradigm, BCBS's pharmacy benefit manager, at (410) 785-2137.

Post Scripts

- R According to a study published in the May issue of *The Journal of Reproductive Medicine*, almost 687,000 unintended pregnancies could be prevented each year if women who use birth control pills properly followed the contraceptive instructions. Representing one-fifth of all unplanned pregnancies, these pregnancies resulted in more than \$2.6 billion in indirect and direct costs, including medical services and lost work time.
- R Key Pharmaceuticals has announced the immediate availability of IMDUR (isosorbide mononitrate) Extended Release Tablets, 120mg. Available in package sizes of 100, IMDUR has a published AWP of \$144.90.
- R Depakote (divalproex sodium) is now indicated for the treatment of manic episodes of bipolar disease, also known as manic-depressive illness. Depakote, marketed by Abbott Laboratories, is the first medication indicated for manic episodes associated with bipolar disorder in 25 years.
- R Merck has announced a new product, Trusopt (dorzolamide HCL ophthalmic solution). Trusopt is the first topical carbonic anhydrase inhibitor indicated for the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma. Drops are administered three times daily.



Marylanders Making News

MPhA members have been garnering more than their fair share of publicity recently. Past President Nicholas

Lykos was presented

with the Baltimore County Department of Economic Development's Business Award for a Small Retail Business. Lykos Pharmacy and State Drug Store were both selected for valuable and quality service.

Trustee **Tim Lubin** and member **Ruth Blatt** have been selected to attend the APhA/SmithKline Beecham Community Pharmacy Management Program at the University of Wisconsin. Only 30 pharmacists nationwide are accepted each year to the program.

In a break with tradition, the Care Drug Centers President's Award was given to two worthy candidates at Care's recent Stockholders Meeting in Williamsburg. **Melvin Chalet** and **Leo Mallard** received the award from Care President Ed Dillon.



Maryland Pharmacy Event Calendar

- June 18-21 MPhA Annual Convention, A New Frontier for Pharmacy,
Ocean City
- June 28 David Stewart Associates Event, Center Club, Baltimore.
Call Theresa at (410) 706-8475.
- July 13-16 AmeriSource "Celebrate the Music" 9th Annual Trade Show, Opryland Hotel, Nashville, TN
- August 13 Washington County Seminar and Picnic. Call Chris Brown at (301) 739-2780.
- Oct 8-11 NARD Annual Convention, Las Vegas, NV. Call (800) 544-7447.
- Oct 20-21 MSHP Annual Seminar, Sheraton Society Hill Hotel, Philadelphia, PA.
- Oct 28 BMPA Annual Dinner Dance and Awards Banquet, Sheraton Towson
1996
- Feb 25 MPhA Mid-Year Meeting, Loews Annapolis Hotel, Annapolis, Maryland.
- March 10 AZO Fritz Berman Memorial Seminar, "Diseases of the Eye"

The following events are co-sponsored by the Maryland Pharmacy Continuing Education Coordinating Council and are **ACPE approved** for pharmacist continuing education credits:

- June 18-21 MPhA Annual Convention (1.1 CEUs). Call (410) 800-833-7587
- July 12 MSPEN CE Seminar (0.1 CEU). Call (410) 880-8233
- August 5-6 ASCP Regional Meeting (0.6 CEUs). Call (703) 739-1300

For more information on having **your** live or home study program **ACPE approved**, contact CECC Coordinator Anna Leonhardt at (410) 727-0746.

NEWSLETTER

The Maryland Pharmacists Association

650 Lombard Street
Baltimore, Maryland 21201



MARYLAND PHARMACIST

June, 1995

Vol. 71, No. 6

- **Legislative Overview**
- **Mind Drugs**
- **CE: FDA Warnings**
- **A Valiant Fight**
- **"Rights" of Spring**
- **Interactions**



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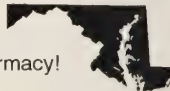


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MARYLAND PHARMACIST

The Official Publication of The Maryland Pharmacists Association

June 1995

4 President's Commentary

MPHA President Arnold Davidov issues a special invite to all MPHA non-members. Benefit yourself and your profession with a nominal investment.

5 And the Gavel Fell

The 1995 Maryland General Assembly concluded its business in April. MPHA lobbyists Robin Shaivitz and Julie Buchwald present the wins and losses for pharmacy in this review article.

10 Pharmacists Battle for Fairness

What happens when pharmacists get fed up with a reimbursement reduction? They take their case to Maryland's highest court. This look at four valiant pharmacists' efforts proves you can win even when you lose.

13 Interactions

Dean David Knapp looks back on the career of retiring Professor Ralph Shangraw and his many contributions to the profession.

14 Oh, To Be Young Again

Tired of hearing about everything you do wrong? This month, Maryland Board of Pharmacy Secretary Mel Rubin tells you about everything you do right!

17 Litigation Update

Are compounded OTC's the reason for this patient's hypertensive crisis? Regular columnist David Brushwood looks at an interesting case.

18 At Issue

Should our society condone the use of drugs for mental cosmetics? Pharmacy student Lisa Hurowitz thinks we should.

22 Continuing Education

This month, we present the accepted and proposed FDA changes to warning labels on OTCs. Don't forget to complete the CE quiz on page 30 for credit! It's free for all MPHA members.

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President's Commentary

There's Just Not Enough Time -- Part Two

In my "Commentary" last month, I talked about how there never seems to be enough time to squeeze in all the meetings, activities, and educational opportunities that are available to pharmacists. And then to try and balance them with a full-time job, family obligations, home, community involvement.... well, you know what I mean. It's practically impossible.

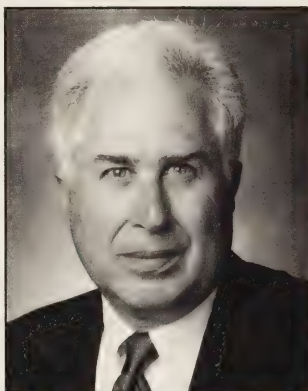
As I complete my term of office as President of the Maryland Pharmacists Association, I can honestly tell you there really *isn't* enough time.

When I took office last June, I thought that there would be plenty of opportunities to launch and complete some pretty ambitious goals. Looking back, I realize that even though some of those goals have been completed, many more are just getting off the ground. Perhaps the most frustrating thing about being a volunteer officer of any organization, even one that is as strong as MPhA, is that there are so many issues, so many really great ideas, and just so little time.

For example, your organization committed more than seven long years and about \$100,000 to fight for legislation that preserves the right of individual patients to choose their pharmacist. MPhA believes that one thing we cannot allow to change in this topsy-turvy world of health care was the right of patients to establish long-term relationships with a pharmacist. You can't create or maintain those kind of connections when your patients are with you one year and gone the next. And certainly not when an employer or an insurance company decides to change their health care programs at seemingly monthly intervals.

Who could have thought that such a fundamentally "right" issue would take seven years of hard work by our members, our lobbyist, our staff, and Board and Committee volunteers? Who could have imagine that such a goal would eat up so much of the one truly finite resource we have, time?

There have been some wise investments of time, too! Our new Pharmaceutical Care Committee worked to plan an exceptional series of educational programs for pharmacists who are ready to accept the challenge of changing the way we practice. Some of these programs are one-day seminars; others have been incorporated into our Annual Convention. Have I accomplished my goal of starting us down the road towards pharmaceutical care? Yes and no. We've started, but we sure aren't there yet!



Arnold Davidov, P.D.
1994-1995 MPhA President

I've had the privilege of meeting a number of you at MPhA and local organization meetings. That truly has been time well spent. You've told me what you like (and dislike) about MPhA; where you want to go (and not go) as professionals, as individuals, and collectively as pharmacy; what MPhA can do (and not do) to help you achieve your own goals. These things I have shared with my successor, Jim Tristani, the MPhA Board of Trustees, and our staff.

One important investment in time and in money has been the decision to send this journal to every pharmacist in Maryland. I have heard more positive comments on this one commitment than practically anything else our organization has ever attempted. I think we have done an exceptional job in showing those pharmacists who aren't members of MPhA just what kind of work and accomplishments are being done and made by our members.

One last thought on time. For those of you who aren't members, isn't it about time you joined? Non-members received an application and membership information with this issue of the journal. And, because I don't have enough of it, I've made sure that joining takes only a few seconds of checking boxes and throwing the form into an envelope. Maybe those few moments spent joining might be your wisest use of time ever! I know it certainly has been mine.



MP

And the Gavel Fell

A Report on the 1995 Legislative Session and Its Impact on Maryland Pharmacists

*Robin Shaivitz and Julie Buchwald,
MPhA Legislative Consultants*

With the 1995 Legislative Session behind us, it's time to review your Association's activities on behalf of the profession.

HB 724/SB 449 The Patient Access Act

Congratulations! After years of hard work, the Maryland Pharmacists Association and its allies were successful in passing a Patient Access bill! Patient access, defined as a consumer's right to choose the provider of their choice, has been one of the organization's long-term priorities. This year, however, MPhA worked with other provider groups -- including physicians, psychologists, podiatrists, dentists -- in efforts to pass this legislation. As in the past, our opposition came from the HMO industry, which chose to masquerade under the name of "The Coalition for Affordable Health Care." As a result of intense lobbying efforts and a "grass-tops" letter and phone-call campaign, our efforts will be recorded in the law of Maryland.

Although the identical bill, as designed by the Provider Coalition, was introduced in both chambers of the General Assembly, the final House and the Senate versions had several variations, thus necessitating that a Conference Committee convene to iron out the differences.

The House of Delegates version, HB 724, provides that certain "due process" standards or "rules of engagement" apply when a health care provider like a pharmacist is seeking inclusion in or is being removed from an HMO's or insurer's benefit network. This bill also included a "mandatory offering" provision. This means that an employer must offer each employee a choice between a plain vanilla HMO with closed networks and a "Point of Service Plan." The bill also provides that in the event a provider is removed from a network, his or her patients will be able to receive covered treatment from that provider for 90 days thereafter.

Chairman Mike Busch and the House Economic Matters Committee also added a provision which forbids the use of withholdings or bonuses when the bonus is offered as an inducement for an in-network doctor to deliver "less"

care (i.e. fewer tests ordered, fewer out-of-network referrals and fewer referrals to specialists).

The Senate version of the bill, SB 449, is markedly different. Although SB 449, as passed by the Senate, includes similar "dues process" standards and the mandatory offering, there are additional issues addressed in this bill. SB 449 provides that a carrier must make the standards which it uses in determining membership in its network available to all applicants. In other words, they must give a pharmacist a list of the criteria that he or she must meet in order to join the network. A major problem for pharmacists, as well as other providers, is that many network managers have no published or accessible data on exactly what they expect from an applicant. Furthermore, in the case that a carrier rejects a provider's application for participation in the carrier's provider panel, the carrier *must* inform the provider in writing why the application was rejected.

The bill further extends provisions of Section 19-705.1 of the Health General Article addressing standards of care to all carriers. SB 449 also establishes that a carrier may not deny an application or terminate a provider's participation on its panel solely on the basis of the license, certification or other authorization of the provider to provide services within the provider's lawful scope of practice. This was very important to pharmacy; without such language, a benefit network could establish a network of dispensing physicians and eliminate all pharmacies.

On Friday, April 7, members from the House of Delegates and from the Senate were appointed to a Conference Committee and began the negotiation process. There was a great deal of secrecy surrounding the process; fortunately we had spoken to key people who we thought might be put on the Conference Committee and who would be supportive of our position. Senators Thomas Bromwell (Chairman, Senate Finance Committee), Larry Young (Chairman, Health Subcommittee of Senate Finance) and John Pica represented the Senate. Delegates Mike Busch (Chairman, House Economic Matters), John Donoghue (Chairman, Health Subcommittee of House Economic Matters) and Charlie McClenahan represented the House.

After hours of tense negotiation, the conference Committee report emerged for consideration by each chamber on the evening of the last day of the Session. With only a few hours left, the report represented a good compromise. Although we lost the precise language addressing the disclosure of standards used by the HMOs, the Committee preserved language prohibiting discrimination based solely on license, degree, or other authorization held by the provider. The report also included language banning the use of withholds and bonuses to the extent that they were used to encourage "less" care. The withholds language has an effective date one year later than the remainder of the bill. The bill also includes language providing for a summer study of Medicaid.

All in all, this is great news for pharmacists. This year marks the beginning of the decline of the HMO's influence in Annapolis. Patients have had bad experiences with their HMOs, they're angry and they are letting their legislators know. If one lesson is to be learned from this success it is the importance of the patients' perspective -- the legislators read their letters and heard their complaints.

HB 513/SB 290

Fairness in

Drug Pricing is a good bill whose time, unfortunately, has not yet come. The bill would have required that manufacturers of prescription drugs must sell drugs to all purchasers on the same terms and conditions. In other words, arbitrary "classes of trade" between similar competitors (community pharmacies and mail order, for example) would have been illegal. The bill would not have prohibited bulk purchase or other similar trade discounts. Despite all the intense efforts of MPhA, EPIC Pharmacies, and the Maryland Association of Chain Drug Stores, the bill died in the House Economic Matters Committee. As was anticipated, the pharmaceutical manufacturers came out in force to oppose our bill.

In a last ditch effort to revive the legislation, an attempt was made to amend the bill in the Senate Finance Committee. We tried to reword the bill to provide for mandatory disclosure of pricing discounts, but this was unsuccessful because the Committee's members were unwilling to reconsider the bill.

HB 351/SB 310

Off-Label Use of Drugs

This Session marked a return to the issue of off-label use of drugs. Last year a bill passed which required insurance companies to cover a patient's use of a drug for purposes other than those which have received FDA approval. Because many manufacturers cannot afford the financial and time commitment necessary to obtain FDA approval for new indications, some insurers and HMO's were using this as an excuse to deny coverage.

This year House Bill 351 and Senate Bill 310 were introduced to close a loophole in the law. Last year's bill left the question as to whether HMO's were subject to this law unanswered. HB 351 and SB 310, as passed, now requires HMO's to reimburse for such usage.

SB 694

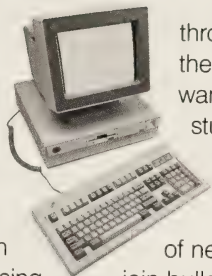
Medicaid Program Expansion of Eligibility Through Managed Care

was passed by the General Assembly and awaits the Governor's signature. The bill gives legislative endorsement for the State to pursue a HCFA 1115 waiver which would require all Medical Assistance services through a managed care plan. SB 694 was amended to give more Legislative oversight in the applications process. Although this may be comforting to the Legislature, this is a double edged sword because the Legislature's increased role may diminish the likelihood of application's approval. The bill, as passed, further allows for community providers to deliver health care

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services under the program if they can establish a requisite level of financial solvency. This level will be determined based on the degree of risk assumed by the provider.

SB 275 Board of Pharmacy Membership

The bill easily passed the Senate and then was referred to the House Environmental Matters Committee. After discussions with Chairman Ron Guns, we came to the conclusion that the process that MPhA followed before the sunset review of 1992 can be followed now as long as MPhA continues to solicit Board membership from all licensed

pharmacists regardless of their membership in MPhA. SB 275 was more restrictive than MPhA's current policies and practice. Therefore, we requested that the bill be defeated and the Committee acted accordingly.

SB 329 Pharmacist Rehabilitation Committee Funding

authorizes the Board of Pharmacy to allocate money from the State Board of Pharmacy Fund to a pharmacist rehabilitation committee. The bill passed as originally presented by Senator Hollinger and was supported strongly by MPhA, the Board and the Maryland Society of Hospital Pharmacists.

All in all, this year's legislative session represented some major and minor gains for pharmacy. Clearly, this is directly attributable to the strong support of MPhA's legislative priorities by you, the pharmacists of the State, and by the commitment of individual volunteer leaders like President Arnold Davidov, President-Elect Jim Tristani, Health Care Policy & Legislation Committee Chairmen Phil Marsiglia and Ernie Testerman, and the MPhA staff.

MP

Supporting the Profession

Profiles of Pharmacists and Industry

This Month: Bristol-Myers Squibb

Bristol-Myers Squibb Company was founded in 1887 by William M. Bristol and John R. Myers in Clinton New York. They invested \$5,000, a princely sum at the time, into a near-bankrupt business neither man knew anything about: ethical pharmaceuticals. Bristol-Myers Squibb has grown rapidly over the years with its greatest growth coming from the merger with Squibb Corporation in 1989. Squibb had been founded by Dr. Edward Robinson Squibb.

Today, more than 100 years after the company's founding, Bristol-Myers Squibb has transformed from that risky \$5,000 investment into a \$12 billion, diversified global health and personal care company with over 47,000 employees worldwide and thousands of products marketed in more than 130 countries. Forty percent of the company sales are from operations outside the United States. Incorporated in 1933, the company's worldwide headquarters is at 345 Park Avenue in New York City.

Today, Bristol-Myers Squibb is comprised of four core businesses: pharmaceuticals, consumer products, medical devices and nutritional products. If there is one theme that runs through all of its product lines and categories, it is this: Bristol-Myers Squibb is in businesses whose products help to enhance human life. The company's goal is to be the preeminent market leader -- that is, to hold the number one or number two position in each product category in each geographic market in which it competes.

Pharmaceuticals

Bristol-Myers Squibb is the third largest pharmaceutical company in the United States and the fourth largest in the world. It is the leading anti-cancer drug company worldwide and the number two company worldwide cardiovascular therapies. It also holds strong leadership positions in anti-infective and dermatologies.

Bristol-Myers Squibb also has a growing position in the central nervous system category and recently initiated new discovery programs in diabetes and immunologic diseases. It markets products or conducts research in AIDS, depression, anxiety, Alzheimer's disease, hypertension, atherosclerosis, stroke and other serious disorders.

The Pharmaceutical Research Institute (PRI), Bristol-Myers Squibb's pharmaceutical research arm, employs 4000 scientists and support personnel with 18 facilities in 12 countries around the world. The company spends over \$1 billion annually on research and development and is actively engaged in research that involves the use of molecular biology, recombinant DNA, monoclonal antibodies and molecular modeling in the search for innovative, cost-effective therapies. The company also holds a leadership position in the growing field of generic drugs. Its Apothecon subsidiary sells some of the most frequently dispensed generic medications in the country.

Consumer Products

Though nearly 60 percent of the companies sales come from pharmaceuticals, Bristol-Myers Squibb is also a leading producer of consumer products, nutritional products, and medical devices-freeing it from over dependence on any single marketplace or product line. Bristol-Myers Squibb has two worldwide consumer products divisions which hold leadership positions in the categories in which they compete. It develops and markets analgesics such as Excedrin, Bufferin, and Nuprin, Comtrex, Theragran vitamins and Keri skin care products. Bristol-Myers Squibb also develops and markets personal care products such as Ban anti-perspirants and deodorants. Worldwide Clairol is the market leader in the United States and number two in the world for haircolorings. Its brands have become household names. Matrix Essentials, acquired in 1994, is one of North America's leading developers and marketers of professional hair and beauty products sold exclusively to beauty salons.

Nutritionals and Medical Devices

The Mead Johnson Nutritional Group has the second largest routine infant formula business in the world. Enfamil, ProSobee, and Nutramigen are just a few of many well known brands. In addition, Mead Johnson produces the broadest range of specialty formulas by any company for infants born with serious nutritional disorders and a variety of adult nutritional supplements as well. Bristol-Myers Squibb medical devices divisions all hold world leadership positions in their respective markets. Zimmer produces artificial hip and knee joints as well as fracture management products and powered surgical instruments. Linvatec produces arthroscopy products, and ConvaTec produces a full line of ostomy and wound care products.

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based on price.**

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based on price either.**

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Pharmacy Partnership

Bristol-Myers Squibb continues to partner with the profession of pharmacy toward achieving mutually beneficial goals. Participation and sponsorship of programs and meetings with local, regional, and national pharmacy organizations remains an important part of the company's objectives of enhancing quality pharmaceutical care. The Bristol-Myers Squibb Continuing Pharmacy Education Monograph series has also assisted in filling the education requirements of pharmacists. In addition, pharmacy access to patient information and compliance programs has further supported the pharmacy profession in providing services and proving value to their customers and patients.

For further information on Bristol-Myers Squibb services for pharmacy, please contact the Customer Service Center at (800) 332-2056, your local representative, or Ron Poppel at (410) 956-5577.

MP

Pharmacists Battle For Fairness

*A Summary of
"Weiner v. Insurance Administration"*

*Julie Buchwald, J.D.
Robin Shaivitz and Associates, Ltd.*

In December 1992, Blue Cross and Blue Shield of Maryland (BCBSM) filed a form of contract with the Maryland Insurance Administration for approval pursuant to statute. The filed form represented a proposed contract between BCBSM and voluntarily participating pharmacies and established a new formula for reimbursement to pharmacies for filling enrollees' prescriptions. The form was approved on March 31, 1993, and the Maryland Pharmacists Association, through its counsel Joseph Kaufman, requested a hearing regarding the propriety of the new reimbursement formula. On May 11, 1993, Associate Insurance Commissioner, Donald Brandenburg, conducted an "informational hearing." Counsel for the Commissioner emphasized that it was not a "quasi-judicial proceeding" and thus did not provide an adjudicatory hearing to those pharmacists who believed that the reimbursement reduction was inappropriate and unsubstantiated by Blue Cross.

Procedure

Four independent pharmacists (Phillip Weiner, Leo Mallard, Dennis Hager, and Gerard Herpel) with support from MPhA, filed suit in the Circuit Court for Baltimore City. The Circuit Court denied the pharmacists' claim that they had been improperly denied a hearing. The pharmacists then appealed to the Court of Special Appeals. Prior to any consideration, the Court of Appeals (the highest court in Maryland) assumed jurisdiction on its own motion.

Issues

MPhA and the pharmacists raised four issues on appeal; only one, however, was addressed by the Court of Appeals. The only issue addressed by the court was whether the pharmacists should have been granted an adjudicatory hearing on their complaints before the Insurance Commissioner. Two other issues were not considered as they were rendered moot by the resolution of the aforementioned inquiry. The last issue was not considered because it had not been properly preserved for appeal.

Holding and Rationale

The Court of Appeals unanimously denied the pharmacists claim that they were entitled to a quasi-judicial hearing before the Insurance Commission asserting that "a party is entitled to a quasi-judicial hearing before an administrative agency only if that type of hearing is required by statute or regulation or mandated by constitutional due process concerns." (Citation omitted). Upon stating, the Court turned its attention to the applicable statute. Article 48A, Section 356, requires that the terms and provisions of the contract to be executed by a non-profit health service plan (Blue Cross) and the plan's subscribers be submitted to the Insurance Commissioner for approval. Subsection (a) provides that "a filing shall be deemed approved unless disapproved by the Commissioner...". The Court concluded that the absence of an explicit provision for a hearing meant that the legislature did not intend that a hearing was necessary. The Court supported this assertion by citing subsection (c) of the law which explicitly provides for a hearing when a filing is determined to be insufficient.

Article 48, Section 242B, governing the review by a court of the Commissioner's decision, was then considered. When considered in conjunction with the aforementioned Sections, the Court concluded that no hearing was required.

The Court further reasoned that legislative intent and notion of separation of powers buttressed the propriety of denying the hearing. The Court asserted that, "...the General Assembly, in providing for judicial review of actions by administrative agencies, may not confer upon the court the ability to review quasi-legislative decisions by substitution of the court's judgment, as to the wisdom of the administrative action, for that of the agency." (Citation omitted). The court proceeded by stating that any judicial review would be restricted to determining whether the agency acted constitutionally or within its "legal boundaries". In evaluating the propriety of the Commission's actions, the Court opined that the Commissioner had properly focused on the effect that the proposal had on the plan's subscribers. The Commissioner's determination was characterized as legislative in nature and thus the Court was reluctant to reverse it.

The Court summarily dismissed other grounds asserted by MPhA in support of its position that it was improperly denied a hearing. The Court determined that Maryland's Administrative Procedures Act (APA) did not provide for a hearing in this case. The Court reasoned that the situation could not be characterized as a "contested case", as the APA required, as the proceeding before the Commissioner was only for the purposes of fact-finding in order to determine if the proposed contact form was "unjust, unfair, inequitable, inadequate, misleading, deceptive, or encourage(d) misrepresentations ...". Pursuant to this conclusion, the Court also

found that Article 48A, Section 35, which provides for review conducted in accordance with the APA was inapplicable. (Furthermore, this provision was not in legal effect during the period which gave rise to this litigation).

Finally, the court asserted that denial of an adjudicatory hearing was not in violation of MPhA or its members due process rights. The Court asserted that "a judicial or trial-type hearing is not a requirement of procedural due process where an administrative agency does not act in a quasi-judicial capacity and the facts to be determined are legislative rather than adjudicative in nature." As previously noted, this court, based on longstanding precedent, categorized the Commissioner's authority to approve rates and forms as a quasi-legislative function. Therefore, protections of due process were not violated.

Conclusion

The Court of Appeals of Maryland, the highest court in the state, thus denied MPhA's contention that it had improperly been denied a hearing before the Insurance Commission based on state and federal statutory basis as well as on Constitutional grounds.

While unsuccessful this case, on behalf of all pharmacies that contract with a non-profit health service plan like Blue Cross, does demonstrate the importance of pursuing "due process" rights. Whenever a governmental agency makes a decision that impinges on a business or profession, those affected must be willing to stand up for what they believe to be right. In this, the four pharmacists and the Maryland Pharmacists Association did win their case.

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Interactions...

Ralph Shangraw

Imagine a 24-hour period that begins with dinner at your favorite restaurant in Little Italy with 80 of your closest friends. It continues the next day with seven hours of speeches all about you and what you've done to make other people's lives better and happier. And it all ends with a reception in a hotel ballroom so crowded with well wishers that you can't even get a slice of your own cake! Sound like a fantasy? Well, it isn't! All it takes, for example, is 46 years of preparation. You could have learned how simple it was by listening to Ralph Shangraw's talk "Forty-Six Years in Forty-Six Minutes" at the super symposium staged last month by the School of Pharmacy to honor his lifetime contributions.

Retired from full-time teaching at the University of Maryland since last December, Dr. Shangraw is now Professor Emeritus, devoting his time to the multi-million dollar FDA contract he brought to the School of Pharmacy several years ago. Over 2,500 pharmacists, or close to three quarters of all Maryland alumni, learned quite a bit about pharmacy from Ralph Shangraw as his students. More than a few have related that it was Dr. Shangraw that turned their student careers around, got them on the right track and saw them firmly started on the path to success.

Ralph's efforts have helped keep Maryland in the vanguard of American pharmacy. In a marvelous example of collaboration among the Board of Pharmacy, practitioners, and the School, Ralph Shangraw worked with Frank Ballassone, the Executive Secretary of the Board of Pharmacy, to engineer the country's Professional Experience Program, moving what was at the time a ragtag, post-graduate, apprenticeship requirement of uneven quality into a faculty-supervised, standardized educational program within the curriculum and completed before students graduated. This happened in the late 1960's and it was a tough sell since a year of apprenticeship after graduation in a pharmacy was *de rigeur* at the time. But Ralph was persuasive and the program was successful, not only in Maryland, but also throughout the country.

Ralph Shangraw's research accomplishments have been deceptively simple. He has a knack of identifying the most basic issues, doing some studies, finding some answers, and devoting his time to making sure that those answers are applied in ways that will help the most people. Three examples:

R It had been known for years that nitroglycerin tablets rapidly lost their potency when they reached the shelves of the pharmacy. Yet nobody could figure out why. Pharmacists and patients routinely threw out their old nitroglycerin tablets and replaced them with new, accepting the situation as a fact of life. Except for Ralph Shangraw! He wanted to know why and he did some experiments. He determined that the nitroglycerin was evaporating or leaching from the tablets and that simple changes in the packaging requirements solved the problem. He didn't stop there, of course. He spearheaded efforts through the USP and the FDA to make sure that packaging changes became the standard.

R A woman sent Ralph a bottle of calcium tablets complaining that they didn't dissolve. She was taking them as a mineral supplement and was worried that she wasn't getting anything out of them. She was right! Ralph and his students studied not only the product that was sent him, but also samples of dozens of other commercially-available calcium tablets. More than half of them sat there for days when immersed in a vinegar solution simulating stomach acid. Ralph noted the glaring lack of regulation of vitamin and mineral products and, again, headed efforts by USP and FDA to change dissolution standards and labeling requirements for calcium supplements. It is now possible for people who now take USP standard calcium to receive some benefit rather than an impacted bowel!

R A major problem facing tablet manufacturers in the early days was to make tablets hard enough that they would not crumble in normal shipping and handling, but not so hard that they would not disintegrate and dissolve when swallowed. Formulating and compressing effective tablets was a real challenge.

Continued on page 20.....

Oh, To Be Young Again

*Melvin Rubin, P.D., Secretary and Commissioner
Maryland State Board of Pharmacy*



e are well
into
Spring
young
man and
young
woman --

and since your fancy has probably turned to each other, it doesn't seem appropriate to talk about problems the Board of Pharmacy sees in the profession. Instead, I think I'll use this column to tell you what pharmacists are doing *right*.

That's more the rule than the exception anyway. The great majority of you are practicing as the professionals you are.

You are better educated now. That trend will certainly continue and expand, probably spiral upwards. Most of you are meeting your new responsibilities head on; many of you lining up for more education in the form of the non-traditional Pharm.D. program. Continuing education programs are well attended, with more subject variety offered and expected than ever before. The School's six year Pharm.D. program should turn out a more professional, caring pharmacist, able to communicate with both patients and other professionals.

Pharmacists continue to expand their knowledge into ancillary fields of patient care -- IV medication, nuclear pharmacy, durable medical equipment, home health care. Pharmacists are involved heavily in acute and long term care, in helping geriatric patients by pre-filling syringes and packing medication in various ways to improve patient compliance.

Perhaps the younger pharmacists have been sparked by the OBRA '90 requirements for counseling. Those of us who have been around for a long time just continue to do what we always have done. Although we now use aids such as computers and counseling printouts to expand our abilities to advise patients on the proper usage of medication, there never has been a time when pharmacists did not counsel patients. "Should I take this with food?" "Can I have alcohol with this?" We have been answering those and many more questions for a long, long time.

And, when patients ask "What's good for....?" you have no choice but to triage them. You can't say "Gee, fella, I don't know." You have to recommend a physician visit, a treatment, or explain why no treatment is needed. The confidence that the patient has in you makes them receptive to your advice on both OTC and prescription medications.

Patients are far more aware today of the role of the pharmacist in providing quality health care. Many insist that you use your full range of knowledge to help them -- and most of you do.

Even a negative often has a positive side. Recent publicity of pharmacist errors has sparked a much greater perception in the patient of what they should expect from the pharmacist. They demand professional treatment and that you provide it.

Even skills that were put on hold are coming back to the forefront. I see more compounding now than in previous years. Many years passed when few pharmacists had to compound suppositories. Now, with new progesterone treatments, many have renewed that skill. Some pharmacies call themselves compounding centers and specialize in what was once a common skill -- now a specialty to some extent -- but again becoming a routine service eagerly provided by all.

What is one man's problem is another's opportunity. I see some pharmacists flourishing in this age of cost containment. Those going about business as usual should consider that the blacksmith who learned to repair automobiles stayed in the transportation business and came out just fine.



Groups like as the MPPI-EPIC network and the Care Drug Centers give hope that the era of the entrepreneur is not over, it's just changed. Pharmacy is practiced in many ways and you are adapting to the variations.

Pharmacy associations such as the Maryland Pharmacists Association, the Maryland Society of Health-System Pharmacists, and the Maryland Chapter of the American Society of Consultant Pharmacists continue to expand their roles to be educators and publicists for their members. You have to keep learning to keep up, and the significance of that multiplies as the public perceives your services as being



of value. Many other pharmacy organizations such as the Maryland Pharmaceutical Society, and the AZO Fraternity place great emphasis on the offerings of continuing education. Young and old members alike come to seminars, learn and constantly rekindle their interest in the profession.

We see many of the victories won by the Pharmacy Rehabilitation Committee, those pharmacists who volunteer to bring a fellow colleague who slipped or even fell, back into the mainstream. The Board only knows about cases we refer to the PRC, and we are sure that they have been able to resurrect many other pharmacists who have had the good fortune to seek their help before doing something to cause Board involvement.

We note the large number of pharmacists who sought

the open position as commissioner on the Board of Pharmacy, despite being told how much work there is involved in the position. We certainly can use all the hard workers we can get.

When the Board advertised for a Pharmacist Compliance Officer, more than 20 pharmacists responded. We had a wide selection of experience, knowledge, and enthusiasm to choose from. We chose well, and were sorry we could not have taken several more of the candidates.

We see the MPhA's efforts in Drug Utilization Review which helps to provide cost containment with an emphasis on quality treatment. Richard Baylis's efforts have saved the State literally millions and given the Association ammunition to keep pharmacist fees as close to realistic as the State budget allows.

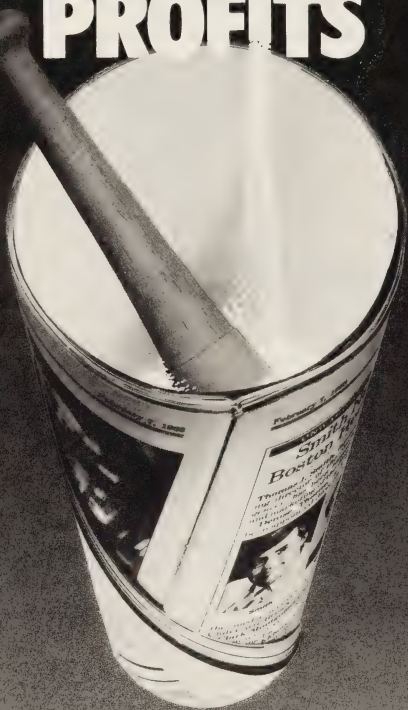
Pharmacy has changed, is changing, will continue to change. The one constant is that the professionalism that you bring to it is needed and is provided.

Now go back to your thoughts before Spring is over.

MP

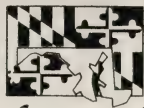


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Litigation Update

Compounded OTCs

David B. Brushwood, R.Ph., J.D.

The Court of Appeal of Louisiana recently affirmed a verdict in favor of a pharmacist who had allegedly caused harm to a patient by failing to adequately supervise the use of an OTC remedy that had been compounded by the pharmacist and dispensed to the patient.

The facts show that the patient had a sinus problem. He had been treated by an allergy specialist for years. One day in September 1990, some friends told him about some medication available at the defendant pharmacy.

The pharmacist at this pharmacy had established a practice of compounding medications with a variety of what he believed to be over-the-counter drugs. There were several of these which he mixed up and gave names like Snoddgrass, Super Snoddgrass, Super de Snuff, Nu-Triphenyl TD, Redeye, Little Read, Goose Grease, and Bec Bottom Balm.

The pharmacist remembered when the patient first came to see him in the fall of 1990. They talked a pretty good time, discussing what the patient wanted and what he thought he needed. The problems. The pharmacist questioned the patient "about his health and things like that, which was normal procedure." "Then," the pharmacist said, "I gave him some medication, one of my formulas that I routinely put together, and told him how to take it and what to expect." They never talked about blood pressure.

The patient later called the pharmacy to complain that the Snoddgrass was not working. He was given Super Snoddgrass. This, too, failed to work, so he also received Super De Snuff. He was finally given Nu-Triphenyl TD.

On the morning of November 14, the patient took his daily dose of Nu-Triphenyl TD. This remedy, like the Snoddgrass and Super de Snuff, contained phenylpropanolamine. Late that afternoon the patient suffered a hypertensive crisis.

At the trial that followed, expert testimony regarding causation was in dispute. Two experts testified that the drug caused the hypertensive crisis, while two other experts testified that the drug did not cause hypertensive crisis. Faced with this conflicting testimony, the jury determined that the patient had not proved his case. It did not matter whether the pharmacist was at fault, because his action did not cause the patient's harm, in the jury's view. This result was upheld on appeal.

MP



David Brushwood

Based On: *Jeans v. Caraway*, 1995 Westlaw 35744 (La. App. February 1, 1995). Copyright 1995, David B. Brushwood. All rights reserved. Reprinted from *Dickinson's Pharmacy*, March, 1995.

At Issue

Cosmetic Psychopharmacology Should it become Standard Practice?

*Lisa Hurowitz, Pharmacy Student
University of Maryland School of Pharmacy*

Psycho pharmacology is the study of the effects of drugs on mental processes and behavior, especially psychotropically active drugs. "Cosmetic psychopharmacology" a term coined by Peter D. Kramer M.D., refers to the therapy of an individual lacking a real clinical need for these drugs. These people are not depressed nor have they some underlying clinical psychosis. Rather, they just want to feel "better than well." They may wish to boost their self esteem, shrug off nasty habits, or just overcome shyness.¹

In this article, I will discuss the reasons why I believe that "cosmetic psychopharmacology" should become an accepted medical practice similar to cosmetic surgery is. Since cosmetic surgery is an option available to all who can afford it to enhance physical appearance, so should drugs be available to enhance perceived mental well-being. I will not discuss any drug specifically since there are so many and their modes of action are quite complex and varied. I am more interested in the overall affect and perception these drugs provide to the user.

According to Harvard University psychologist Jerome Kagan, twenty percent of people begin life with genetically programmed neurochemistry which predisposes them to shyness. Kagan believes that an excess of the neurotransmitter norepinephrine may be the reason to blame for this increased inhibition.² I can view this as a birth defect. Since there are treatments for other kinds of birth defects, why should this not be treated? Since there is an obvious biochemical reason connected to an unwanted behavior it is entirely appropriate that a drug should be indicated to treat it.

In this society, and even in our pharmacy school's curriculum, shyness is not a desirable trait. It is very difficult for someone who is shy and suffers from stage fright to be assertive and speak to a group. There are precedents for treating people for stage fright. An example is Boston Opera oboist Stuart Dunkel. He takes beta-blockers before performances. Without these drugs, playing in front of an audience is almost an impossible task for him.²

A draw back to this therapy is the thought that doctors are actually chemically altering the traits that make us individuals. Kagan believes that there is a reason for shyness to exist in a society. "Some of histories greatest thinkers and creators T.S. Eliot, Emily Dickenson, and Anton Bruckner were shy. Inhibited children tend to wander off into vocations like music, literature and philosophy."¹

I believe that it is an individual's right to choose a career. Should they want to choose a profession that involves public appearances, than it must also be their right to use whatever tools are available to enhance their performance. This in turn would enhance their own sense of well-being, self-worth and accomplishments.

An argument against the use of psychoactive drugs for cosmetic purposes is the belief that we are altering the characteristics that make us individuals. Essentially, we would be creating a society of people that would all be the same. This is the argument that the Church of Scientology uses. The belief that we are playing God by altering the brains chemistry, as claimed by them, is not true. The improvement of an individual's life should be of paramount importance; altering a chemical in the brain to reduce shyness or improve memory will not turn us into robots, but enhance our life. The Scientologists have attacked psychiatry and medicine for a long time without real scientific proof to support up their claims.¹

World class runners are using experimental sports drinks scientifically designed to manipulate neurotransmitters in the brain, during their training runs. These sports drinks work by dumping branched chain amino acids into the brain to prevent the amino acid tryptophan from reaching the brain. Tryptophan is converted into serotonin which causes drowsiness. If runners do not become drowsy then their performance improves. Although none of these drinks have been used during actual marathons, *Runners World* magazine predicts that by the 1996 Olympics runners will be using them during competition.³ I do not see much difference between altering brain chemistry by controlling which amino acids get to the brain or by directly providing a chemical that alters the biochemistry of the brain. You are still playing with brain chemistry.

In fact world class runners have used psychoactive drugs to help their performance. Alberto Salazaar, winner of three New York marathons and a Boston marathon, has benefitted from these drugs. He started doing poorly in races and decided to take Prozac, a psychotropically active drug. His running greatly improved.

These drugs do not work for everyone wanting to increase their sports performance. *Runners World* lists several runners who did not benefit from drugs and who felt their performances suffered from them. Although these drugs did not work for them, at least they had the opportunity to find out if these drugs could help them. The International Olympic Committee has not banned these substances as performance enhancing drugs since the drug actions are highly variable. The Olympic Committee is very careful about not allowing

athletes to use chemicals that artificially enhance their performance.³ I believe that these drugs should be available to all who want to see if they can make an improvement in their life and athletic performance.

Addiction is not an issue of concern with these psychoactive drugs as they do not become addictive to the people who use them. The patients do not become euphoric as compared to the affects of recreational drugs such as cocaine or heroin. Also these drugs do not seem to effect people who really do not need them. Individuals who have taken them for a perceived problem, as opposed to an actual problem, have gained no benefit and discontinued their use.⁴ This to me shows that people who want to try these drugs have very little to risk and a lot to gain. If there is no perceived improvement to themselves then they can stop taking the drugs.

An economic issue can be seen here also. In the past people with psychological or perceived psychological problems might have gone into long term psychotherapy at great expense. Psychotherapy may not work and may be a complete waste of time for both the therapist and the patient if their problem is a simple biochemical imbalance. Prescribed drugs cost must less than hours of therapy. Insurance companies can also benefit from the reduced cost of treatment for these individuals.⁵ Ability to pay has been a hallmark of cosmetic surgery for those with no insurance or for a condition for which there is no insurance coverage. I believe the same thing should apply to drug therapy in those who wish to try "cosmetic psychopharmacology."



Cosmetic psychopharmacological agents should only be available by prescription through qualified health care providers, and should not be available over-the-counter. As with most drugs, potentially harmful side effects and risks exist with psychoactive drugs. An example of a serious side effect is cancer. Both fluoxetine and amitriptyline were given to animals in clinically relevant doses. These drugs were shown to cause cancer in these animals. While this has not been seen in humans, a review of all the potential side effects of a drug should be made so a rational decision to initiate therapy with these agents can be made.⁶ There may be a lag time up to one month between the initiation of drug treatment and any observation of intended effects.

Without careful monitoring by qualified individuals positive therapy outcomes may not be achieved due to the lack of knowledge about these drugs by the users. The user may discontinue treatment early without the desired effect being achieved due to the lack of knowledge of the mode of action of these compounds.⁷ Since there are new drugs being developed all the time, only a health professional can know which drug would be the best for the individual. If people bought these drugs off the street then they would not know what they were getting or how much to take or what life threatening side effects to look for. Self medication could be very dangerous, especially if the individual really needs extensive psychotherapy and mistakenly believes that any drug will help them.

I believe that the practice of cosmetic psychopharmacology, like cosmetic surgery, can be a safe and enhancing therapy if administered and monitored properly. As with cosmetic surgery a poor surgeon will cause an undesirable outcome; an uninformed provider of these drugs could choose the wrong drug and cause a life-threatening disaster. Living in a competitive society can be very stressful; anything that can make life easier and more successful should be considered a valuable tool that should be taken advantage of, which includes the use and practice of "cosmetic" psychopharmacology.

MP

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Interactions

Continued from page 13

Then Ralph Shangraw read a brief article in a chemical journal that came across his desk by chance. It discussed microcrystalline microcellulose, an inexpensive ingredient that could be compressed into a very hard tablet but that would virtually explode when exposed to moisture. Requesting a small sample from the manufacturer, Ralph soon determined that the product was an excellent disintegrant and one that has subsequently become one of the world's most widely-used ingredients in oral dosage forms.

Ralph's continuing efforts to make things easier for other people led him to work with Giant Food to redesign their labeling for over-the-counter products using large labeling pictograms and plainer language. The Giant labels soon became a standard for the industry.

These contributions are just some of the reasons why Ralph F. Shangraw has made an indelible impression on the state of Maryland and the University during his 37-year career. They're also the reason that only a few weeks after announcing a campaign to establish the Ralph F. Shangraw Endowed Chair in Pharmaceuticals, friends of Ralph have pledged over \$350,000 towards the \$1.5 million needed for this purpose. The endowed chair will establish a permanent legacy of the accomplishments of Dr. Shangraw and will enable the School to continue to support the fine work with which his name is synonymous.

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Contributions to the UM Foundation/Ralph F. Shangraw Endowment Fund may be made to Theresa Silanskis, Director of Development at the School of Pharmacy, (410) 706-8475.



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On August 26, 1993, the FDA amended its *Final Monographs for OTC Antacid, Water-Soluble Gum, Antiemetic, and Sleep Aid Drug Products*. In this lesson, the significance of these warnings as they pertain to counseling patients will be discussed.

Antacids

The revised warning for OTC antacids (Table 1) comes nearly 20 years after the original *Final Monograph for Antacid Drug Products* was promulgated by FDA. Interestingly, antacids were the first group of OTCs evaluated after FDA was given the mandate to assure that all drugs (Rx and OTC) were safe and effective.

The initial *Drug Interaction Precaution* (DIP) for antacids published in 1974 referred only to aluminum-containing antacids interacting with tetracycline. This was amended in 1979 to include calcium and magnesium salts. In 1982, FDA was petitioned with a request to add digoxin to the DIP.

Comments on Antacid Labeling

After reviewing the petition and the literature, FDA proposed, in 1986, that the wording be changed to: "Antacids may interact with certain prescription drugs. If you are presently taking a prescription, do not take this product without checking with your physician." In response to public comments, FDA has reviewed the comments and the literature to arrive at the final wording of the antacid DIP.

Recent Changes in FDA-Required Warnings

Affecting OTC Antacids, Antiemetics, Sleep Aids, and Water-Soluble Gums

J. Richard Wuest, R. Ph., Pharm.D.
Professor of Pharmacy Practice, University of Cincinnati

Thomas A. Gossel, R. Ph., Ph.D., Interim Dean
Ohio Northern University

A professional development program made possible by an educational grant from **SEARLE**.

Among the pertinent comments, many requested that the word "pharmacist" be included as a health professional with whom consumers could check with about possible drug interactions. Major points made in these comments included the pharmacist's professional knowledge, ready availability, willingness to provide advice without charging expensive professional fees, access to the patient's medical profile and likelihood that consumers purchase antacids from pharmacies. While FDA agreed with all of these comments, the agency believed, however, that "other health professionals, such as nurses and physician assistants can also help consumers

determine whether the drug they are taking interacts with antacids." FDA decided that "health professional" is the preferred term because it does not restrict consumers from other available sources of information.

Significance of Antacid Interactions

Several comments contended that the proposed DIP is not supported by the medical or scientific literature. When one looks closely at the citations used by FDA to arrive at its conclusion, one finds many review articles that cross-reference each other, many anecdotal notes and letters to the editor, and tertiary articles (e.g., the one you are

reading now). It is difficult to find a well documented, blinded study in patients with diseases that prove there was harm done or that a therapeutic failure resulted from an interaction between antacids and other drugs.

FDA disagreed with this concept and concluded that the entire class of antacids can interact with a wide range of drugs, thereby adversely affecting their efficacy. An argument to support this viewpoint is that there are many potential mechanisms for antacids to affect the bioavailability of other drugs. Examples follow:

1. *Antacids alter gastric pH.* This could also change the ionization of other drugs and, thereby, modify absorption rates. Unionized chemicals are more likely to be absorbed through gastrointestinal cell membranes. By increasing the ionization of acidic drugs, antacids could reduce their absorption. Conversely, antacids could enhance absorption of basic drugs by decreasing their ionization. By changing the pH of the gastric fluids, antacids can increase or decrease absorption of other drugs depending on whether they are preferentially absorbed from the stomach or intestine.

2. *Antacids, most specifically the di- and tri-valent cations, can form poorly soluble complexes or chelates with other drugs.* This could reduce the absorption of the chelated/complexed drugs.

3. *Antacids, especially aluminum salts, can adsorb other drugs to themselves.* This could reduce the absorption of the adsorbed drugs.

4. *Antacids, specifically sodium bicarbonate, can affect urinary pH causing it to be more alkaline.*

This could increase or decrease the rate of elimination of some drugs depending on whether they are weak acids or weak bases. Changes in ionization similar to those explained above (#1) can determine whether the drug is more or less likely to be reabsorbed in the kidneys.

Warning Required on the Labeling of all OTC Antacids*

Drug Interaction

Precaution: Antacids may interact with certain prescription drugs. If you are presently taking a prescription drug, do not take this product without checking with your physician (or doctor) or other health professional.

*Effective 8/23/93.

Table 1

While the significance of the above potential interactions is open to debate, FDA now requires a warning to consumers that they not take antacids without first checking with their doctor if they are taking any prescription drug.

Interactions With Considerable Evidence of Significance

1. *Antacids may antagonize tetracycline.* Di- and tri-valent ions such as aluminum, bismuth, calcium and magnesium may

inhibit the absorption of tetracycline derivatives through chelation. There is some evidence that decreased dissolution of the dosage form is also involved. Concurrent therapy is not contraindicated, but tetracycline and its derivatives should be taken at least two to three hours either side of the dose of an antacid. A once-daily tetracycline derivative (e.g., doxycycline, minocycline) taken on arising, at least one hour before the antacids, might be an alternative causing less likelihood of a problem in patients requiring a tetracycline product concurrently with antacid therapy.

2. *Antacids may antagonize ketoconazole.* Ketoconazole (Nizoral) tablets require gastric acidity for proper dissolution. By raising gastric pH, antacids can reduce the release of ketoconazole from its tablet form and reduce its absorption. Concomitant therapy with antacids is contraindicated, but if needed, the antacid-containing product should be taken at least two hours after the dose of ketoconazole. In this instance, the best time to take a once-daily dose of ketoconazole is in the morning upon arising.

3. *Antacids with sodium polystyrene sulfonate may cause alkalosis.* The therapeutic action of sodium polystyrene sulfonate (SPS/Kayexalate) is to bind with potassium ions in the GI tract and prevent their absorption, thus alleviating hyperkalemia. However, SPS will also bind with calcium and magnesium ions contained in antacids to prevent total neutralization of bicarbonate ions present. This, in turn, can lead to systemic alkalosis which may be severe. If concomitant therapy with antacids and sodium

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polystyrene sulfonate is needed, this interaction is unlikely to occur when SPS is administered rectally.

4. *Some antacids may antagonize quinolone antibiotics.* Some antacids may reduce serum and urine concentrations of quinolone antibiotics (Cipro, Floxin, Maxaquin, Noroxin, Penetrex), possibly by 90 percent. The proposed mechanism for this interaction is reduced absorption due to chelation with aluminum and magnesium ions.

Manufacturers warn that antacids should not be taken within two hours of quinolone antibiotic. Information is lacking on whether calcium salts are involved in this interaction.

5. *Antacids reduce the absorption of cefpodixime.* Antacids raise the pH of gastric contents and decrease the dissolution rate of

cefpodixime (Vantin) tablets. Patients taking Vantin should be told to take their dose between meals on an empty stomach. Antacids should not be taken sooner than two hours either side of the doses of Vantin tablets.

6. *Antacids, specifically aluminum hydroxide, can reduce absorption of isoniazid.* Aluminum salts delay gastric emptying time and can reduce isoniazid absorption. This interaction can be avoided by using an antacid that does not contain aluminum salts, and by taking them at least two hours before or after the dose of isoniazid.

7. *Sodium bicarbonate may antagonize lithium.* Sodium and lithium compete with each other for excretion with sodium being preferentially reabsorbed from the kidneys. Patients taking lithium should not change their sodium intake significantly, and they should definitely not self-medicate with an antacid containing sodium bicarbonate.

Patient Counseling for OTC Antacids

1. Antacids are used to relieve heartburn, acid indigestion, sour stomach, and upset stomach associated with these symptoms. Under supervision by a doctor, antacids are used to treat peptic ulcer disease.
2. When used to treat peptic ulcer disease, antacids should be taken 20 minutes to one hour after meals and at bedtime, or as directed by your doctor.
3. Do not take this medicine within two hours of any prescription drug.
4. With the liquid antacids, remember to shake the bottle well before using. Specially marked devices are available to assure you measure an accurate dose. If you want one, ask for it.
5. For chewable tablets: Chew the tablet well before swallowing.
6. You may follow each dose with a full glass of water.
7. Unless directed by your doctor, do not use more than the recommended dose or larger than two weeks, or if you have kidney disease.
8. If you are on a low salt diet, check to make sure it is okay to use this medicine.
9. Call your doctor if you have problems with constipation or diarrhea.
10. Read all labels before using this medicine.
11. Keep all medicines out of the reach of children and do not keep or use outdated medicines.

A

few other drugs reportedly interact with antacids, but proof of significance is lacking. They

include all lopurinol, anticholinergics, digitalis, folic acid, histamine-2 blockers, misoprostol, penicillamine, phenothizines, phenytoin and sucralfate.

Calcium-containing antacids may interact with a number of drugs. Calcium can antagonize calcitonin and etidronate. Excessive calcium intake can lead to hypercalcemia when taken with potassium-sparing diuretics and vitamin D. Patients taking any of them should avoid calcium-containing antacids.

Sodium bicarbonate, by increasing urinary pH, may affect the reabsorption of other drugs that appear in review articles as having their excretion decreased are amphetamines, ephedrine, mecamylamine, mexiletine, quinidine and tocainide. Salicylate excretion may be increased.

Counseling Considerations

There are at least three scenarios in which the individual patient and physician must be considered when deciding how to counsel a patient:

Scenario One. The physician has specifically told the patient to take an antacid with each dose of a prescription drug. Flatly telling the patient not to do so may not be in his/her best interest. It could confuse the patient because his doctor had specifically directed it. In this instance, determining

whether the physician's intent is to reduce gastric upset when the prescription drug is ingested, and whether all antacids reportedly interact, or is only one cation implicated. For example, only aluminum salts appear to interact with warfarin and only calcium salts interact with thiazide diuretics. In each instance, a product without aluminum or without calcium could be selected and the interaction avoided.

Scenario Two. The patient has peptic ulcer disease (PUD) and the physician has specifically told him/her to "take an antacid."

With this scenario, it might be best to determine whether the symptoms are short-term or periodic and not chronic. If the latter is the case, the patient should check with his/her physician since continuous heartburn, etc., could be symptomatic of PUD, GERD and other gastrointestinal disorders. It could also be a sign that the prescription drug is irritating the gastric lining. In either instance, the patient should be discussing this with the physician.

If the symptoms are temporary (FDA has ruled that after two weeks of continuous symptoms the patient needs medical intervention), the two-hour wait before or after the dose of his prescription drug may alleviate the symptoms and avoid the interaction.

The key point is that no label warning can apply to every person, and each situation must be aimed at maximizing an individual's therapy whether it is supervised or self-treated.

Water Soluble Gum

FDA's final rule for OTC drugs containing water-soluble gums, hydrophilic gums and hydrophilic muciloids as active ingredients addressed the need for specific warnings and directions for proper ingestion. Currently, ingredients that are widely used include methylcellulose, polycarbophil and psyllium, in bulk-forming laxatives.

These products, when added to water, swell and increase their bulk. This is how they act as laxatives. However, if they are ingested with inadequate liquid, they can result in a thick, viscous, semi-solid mass. In patients who have difficulty swallowing, there is a risk that the mass will adhere and block the throat.

OTC products containing water-soluble gums have been commercially available for decades. Until FDA began its drug product surveillance program, there were isolated reports of water-soluble gums causing obstruction problems. Since 1970, however, FDA has received nearly 200 reports of esophageal obstruction and eight cases of asphyxia associated with the use of these products. Death occurred in 18 of these cases.

In its recent announcement, FDA ruled that consumers should be warned of potential problems and how to properly prepare them for ingestion (i.e., with at least eight ounces of fluid). All OTC drug products containing water-soluble gums, hydrophilic gums and hydrophilic muciloids as active ingredient when marketed in a dry or incompletely hydrated form (capsules, granules, powders, tablets or wafers) must bear the warning listed in Table Two.

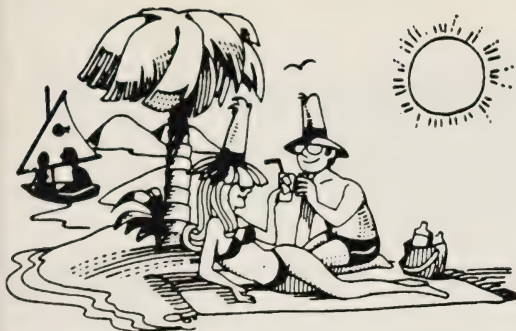
Warning Required on All OTCs Containing Water-Soluble Gums in a Powder Form as an Active Ingredient*

Warning: Taking this product without adequate fluid may cause it to swell and block your throat or esophagus and may cause choking. Do NOT take this product if you have difficulty in swallowing. If you experience chest pain vomiting, or difficulty in swallowing or breathing after taking this product, seek immediate medical attention.

Directions: Take (or mix) this product (dosage) with at least eight ounces (a full glass) of water or other fluid. Taking this product without enough liquid may cause choking. See Warnings.

*Effective 2/28/94

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MPA

Antiemetics and Sleep Aids

FDA also proposed amendments to the current monographs on OTC antiemetics and sleep aids. The premise for the amendments was to bring them in line with the labeling of other OTCs containing antihistamines.

While the warnings are not final, they are worth mentioning since the proposed wording is somewhat different from the current labeling. Presently, OTCs containing antihistamines must bear the warning "Do not take this product if you have asthma, emphysema, chronic pulmonary disease, shortness of breath, difficulty in breathing, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor."

The basis of the proposed change is to replace the phrases "shortness of breath" and "difficulty breathing" with "If you have a problem." The agency state that this will allow consumers to recognize respiratory distress symptoms more readily.

Proposed Amended Warning for OTC Antiemetics and Sleep Aids*

Do not take this product unless directed by a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma, or difficulty in urination due to enlargement of the prostate gland.

*Proposed 8/26/95

Table 3

Patient Counseling for Bulk-Forming Laxatives

1. This medicine is used for temporary relief of constipation.
2. To properly prepare this medicine: Powders: Stir the proper dose briskly in at least eight ounces (a full glass) of fluid before swallowing it. Packets: Pour the contents in an eight ounce glass and slowly add sufficient fluid while stirring. Chewable tablets/wafers: Take at least eight ounces (a full glass) of liquid with each dose.
3. Drinking additional water with each dose is helpful.
4. Do not use this medicine longer than one week or if abdominal pain, nausea, vomiting, change in bowel habits or rectal bleeding are present unless directed by your doctor.
5. This is a bulk-forming laxative. It usually works in 12 to 72 hours. If you do not get the relief you desire after taking this medicine for five days, contact your doctor.
6. Do not use this medicine more frequently or in greater quantity than recommended on the label.
7. Drinking lots of fluids, increasing the amount of fiber in your diet and exercising will help prevent constipation.
8. If you experience chest pain, vomiting, or difficulty in breathing after taking this medicine, seek immediate medical attention.
9. Do not give to children under six years of age unless directed by your doctor.
10. Do not take this medicine unless directed by your doctor if you are pregnant or nursing.
11. For psyllium products: If you are allergic to psyllium, do not take this medicine.
12. Read all labels before using this medicine.
13. Keep all medicines out of the reach of children and do not keep or use outdated medicines.

FDA also replaced the diseases "asthma" and "chronic pulmonary disease" with "chronic bronchitis." The agency did not give its reasoning for the change, but allergy specialists had petitioned that a warning specifically on asthma is not appropriate for antihistamines.

Their opinion is that some individuals have difficulty with the anticholinergic effects of certain antihistamines (e.g., lessened respiratory secretions). This may aggravate their breathing problems and make it more difficult to expectorate. Antihistamines actually constitute proper therapy for other patients since histamine is a factor in allergic reactions. FDA must have agreed with this concept in changing the warning from asthma to chronic bronchitis, which also covers chronic

pulmonary disease. The proposed new wording for the antihistamine warning appears in Table Three. It is not yet finalized and will be part of a future rule, after FDA reviews the comments generated by this proposal.

MP

Patient counseling information provided in this article was adapted from the PharmextPALs (patient advisory leaflets). For more information, call (800) 233-0585.

Patient Counseling for OTC Antiemetics

1. This medicine is used to treat nausea, vomiting, and dizziness of motion sickness.
2. When used for motion sickness, take the first dose 30 minutes before exposure to motion.
3. For liquids: Specially marked devices are available to assure you measure an accurate dose. If you want one, ask for it.
4. For chewable tablets: Chew the tablet well before swallowing.
5. This medicine may cause drowsiness or blurred vision. Do not drive a car, operate dangerous machinery, or perform jobs that require alertness until you know how you are going to react.
6. Avoid alcoholic beverages while you are taking this medicine.
7. Consult your doctor before taking other nonprescription or prescription drugs containing antihistamines, antidepressants, tranquilizers, antianxiety drugs, narcotic pain relievers, sleeping pills, or antibiotics that may cause cardiac damage.
8. Do not take this medicine if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma, or difficulty in urination due to enlargement of the prostate gland, unless directed by your doctor. (If medicine is labeled for children under 12 only, drop the reference to prostate enlargement.)
9. Do not give this medicine to children under six years of age unless directed by your doctor.
10. If you are pregnant or nursing, do not take this medicine unless directed by your doctor.
11. Read all labels before using this medicine.
12. Keep all medicines out of the reach of children and do not keep or use outdated medicines.
13. In case of accidental overdose, call your doctor or poison control center immediately.

Patient Counseling for OTC Sleep Aids

1. This medicine is used to help you get to sleep.
2. Take this medicine 30 minutes before bedtime as directed on the product label.
3. Alcoholic beverages cause increased drowsiness.
4. If sleeplessness continues for more than two weeks, call your doctor.
5. Do not take this medicine if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma, or difficulty in urination due to enlargement of the prostate gland, unless directed by your doctor.
6. Do not take more doses or more than recommended on the label.
7. Read all labels before using this medicine.
8. Do not give to children under 12 years of age unless directed by the child's doctor.
9. Keep all medicines out of the reach of children and do not keep or use outdated medicine.
10. In case of accidental overdose, call your doctor or poison control center immediately.

Continuing Education Quiz

June 1995 -- FDA Required Warnings

This month's questions are taken from the article on revised FDA warnings for OTC products that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. There is **no charge** for this quiz for MPhA members (non-members \$5.00). The completed quiz for this issue must be received by November 30, 1995. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name _____

Address _____

City/State/ZIP Code _____

1. The initial *Drug Interaction Precautions* for OTC antacids published by FDA in 1974 referred to:
 - a. aluminum salts only
 - b. calcium salts only
 - c. magnesium salts only
 - d. all antacids
2. When antacids alter the ionization of drugs in the G.I. tract, they are most likely to affect the interacting drug's rate of:
 - a. absorption
 - b. distribution
 - c. metabolism
 - d. excretion
3. The antifungal agent that is antagonized by antacids because it requires gastric acidity for proposer dissolution is:
 - a. Diflucan
 - b. Fulvicin
 - c. Nizoral
 - d. Sporanox
4. Since 1970, FDA has received nearly 200 reports on which the following is being caused by OTC products containing water-soluble gums?
 - a. Anaphylactic reactions
 - b. Esophageal obstruction
 - c. Large bowel inflammation
 - d. Nutritional malabsorption
5. The best time to take an antacid is:
 - a. morning and evening
 - b. 20 to 60 minutes after meals and at bedtime
 - c. during the meal
6. The current *Drug Interaction Precautions* for OTC antacids published by the FDA in 1993 refers to:
 - a. aluminum salts only
 - b. calcium salts only
 - c. magnesium salts only
 - d. all antacids
7. Which is most likely to affect urinary pH?
 - a. Aluminum hydroxide
 - b. Calcium carbonate
 - c. Magnesium trisilicate
 - d. Sodium bicarbonate
8. Antacids are most likely to reduce the serum and urine concentrations of which of the following groups of anti-infective agents?
 - a. Macrolides
 - b. Penicillins
 - c. Quinolones
 - d. Sulfonamides
9. OTC antiemetics must bear a warning on their label advising consumers not to self-medicate with the product if they have which of the following diseases?
 - a. Acute angina
 - b. Chronic bronchitis
 - c. Diabetes mellitus
 - d. High blood pressure
10. Which of the following has a warning on its labeling advising against using the product longer than one week or if abdominal pain occurs?
 - a. Antacids
 - b. Antiemetics
 - c. Laxatives

CLASSIFIED ADS

Services

20% DISCOUNT on awards, plaques, trophies, and engraving to MPhA members. Call Rudy Winternitz, P.D. at Washington Trophy Center, (202) 966-1255.

BILLING PROBLEMS? We are "the" experts in problem reimbursement. We have over a dozen years experience in the pharmacy billing field, and seven in the infusion/home care industry. Even if you think your practice is going well, let us give you an estimate of how we can increase your reimbursement. Call now for a prompt, professional and personal billing service. Call (410) 282-0285.

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Rx LICENSE TAGS are still available! A special benefit "for members only" that costs only a nominal fee. If interested, call Mary Ann at the MPhA offices toll-free, (800) 833-7587.

PHARMACISTS: prn PLACEMENT AGENCY for temporary and permanent placement. Fine out why more and more pharmacies are turning to PHARMACISTS: prn to fill all of their pharmacy staffing needs. Only 10% permanent placement fee, with 60 day guarantee. Temporary staffing services also available. Competitive prices. Rates for temps include all payroll taxes, FICA, workers' comp, liability insurance, etc. Almost a decade in providing pharmacy personnel services in every practice setting. Call PHARMACISTS: prn at (800) 832-5560.

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(800) 833-7587 toll-free in Maryland
(410) 727-2253 FAX

Mid-Atlantic DUR, Inc.

(410) 727-6122
(800) 833-7587 toll-free in Maryland

MSHP Offices

720 Light Street
Baltimore, Maryland 21202
(410) 752-3318
(410) 752-8295 FAX

Maryland State Board of Pharmacy

4201 Patterson Avenue
Baltimore, Maryland 21215
(410) 764-4755

Maryland Division of Drug Control

4201 Patterson Avenue
Baltimore, Maryland 21215
(410) 764-2890

Towson Travel Center

MPhA Cruises and Trips
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Sheraton Ocean City Resort

MPhA Convention Site - 1994
10001 Coastal Highway
Ocean City, Maryland
(800) 638-2100

Loews Annapolis Hotel

MPhA Mid-Year Site - 1996
126 West Street
Annapolis, Maryland 21401
(410) 263-7777

American Pharmaceutical Association

2215 Constitution Avenue
Washington, DC 20037
(202) 628-4410

N·A·R·D

205 Daingerfield Road
Alexandria, Virginia 22314
(703) 683-8200
(800) 544-7447 toll-free

Placing an Ad

Have something to sell, rent, or trade? Need a pharmacist? Looking for a new position? MPhA members can place a classified ad in *The Maryland Pharmacist* for free. MPhA will remove member ads after six months unless otherwise notified by the member. Non-members may also place a classified ad. The ad placement charge is \$10 for a maximum of 50 words plus 50 cents per word greater than 50. To place an ad, call MPhA at (800) 833-7587.

Next Month:

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NEWSLETTER

The Maryland Pharmacists Association

650 Lombard Street

Baltimore, Maryland 21201

(410) 727-0746

Time's Running Out

It's that time again. Renewals for pharmacist licenses are scheduled for mailing this summer. If your license ends in an odd number, it's your year to obtain a renewed license.

Now is the time for you to check your continuing education credits. You'll need a total of 30 credit hours dated between October 1, 1993, and September 30, 1995. In addition to signing and returning the renewal application with your payment, you will also be required to complete a continuing education credit report form. This form asks for the name, date, and credits earned for your continuing education.

If you don't already have 30 credits, call the MPhA offices for assistance at (800) 833-7587. If there's no way you'll be able to earn all the required credits by the renewal deadline, call the Maryland State Board of Pharmacy at (410) 764-4755 or toll-free at (800) 542-4964.

Welcome New Members

A special "hello" to 15 new MPhA members:

| | |
|-----------------|------------------|
| Charles Downs | Renee Farmer |
| Rebecca Feld | James Gass |
| Marvin Goldberg | Kim Heimberger |
| Aldric Jameson | Marni Levenson |
| Wilson Neighoff | D. Nemeth-Barath |
| Suketu Raval | Donna Robinson |
| Irwin Ruben | Karen Tafoya |
| Lawson Williams | |

July/August 1995

The MPhA Newsletter is published monthly except during the months of July and August when the issues are combined. For information about any article contained herein, contact MPhA at (410) 727-0746 or toll-free at (800) 833-7587. President: James Tristani, P.D.; Chairman, Board of Trustees: Arnold Davidov, P.D.; Production Manager: David Miller, P.D..

Annual Convention A Big Success

A near-record crowd gathered at the Sheraton Ocean City Resort Hotel for the 113th Annual MPhA Convention in June. High-profile speakers and a lively debate on policy issues were just two of the focal points of the four day event. And dominating the discussions was how MPhA can better represent the needs and issues that affect employee pharmacists.



In addressing the attendees, newly installed MPhA President Jim Tristani stated, "We must examine the problems of employee pharmacists and single pharmacy proprietors who today are being called upon to dispense large numbers of prescriptions, provide some manner of patient counseling, and find themselves spending more time with an insurance company than the patient. We cannot permit the sweatshop mentality that has pharmacists working six, eight, or twelve hours without a break. We cannot permit our members and the pharmacists of Maryland to be placed in a position where filling too many prescriptions result in too many errors." A new MPhA policy on employee pharmacists was adopted during the House of Delegates meeting on June 20. Complete details on new policies appear in the August issue of *The Maryland Pharmacist*.

In addition to the business and continuing education sessions, pharmacists elected **Mark Sanford** to Speaker and **Crystal King** to Vice-Speaker of the House of Delegates. Sanford and King both take positions on MPhA's Board of Trustees to ensure that the policy decisions made by the membership are acted upon by the Board of Trustees.

Spigelmire Dies

A Maryland pharmacy institution, **Charles Spigelmire**, died of pneumonia following a long-illness on Saturday, July 15, 1995, in Baltimore. Spigelmire's accomplishments and friends are so numerous as to be almost impossible to list. In addition to serving more than 30 years as Treasurer for the Baltimore Metropolitan Pharmacists Association and many positions within MPhA, Dr. Spigelmire was a two-time recipient of the Seidman Distinguished Achievement Award and a recipient of the Wyeth-Ayerst Bowl of Hygiea.



ACA Presents Specialty Training

The American College of Apothecaries Pharmaceutical Care Institute will present a second Specialty Training Program in Respiratory Diseases in Memphis, Tennessee, December 13-17, 1995. Pharmacists from across the US will spend more than 40 hours in an intensive clinical education experience to prepare them to develop a specialty practice in respiratory therapy. Demonstrations and training in the use of peak flow meters, metered dose inhalers and spacer devices will also be provided. For information and registration materials, call ACA at (703) 684-8603.

The Name Game

A frustrating issue for pharmacists was one of the topics discussed during the MPhA House of Delegates meeting during the 113th Annual Convention. And that issue centers around the confusing use of brand names by OTC manufacturers.

More manufacturers of OTCs are capitalizing on established name recognition by marketing "families" of products under that established name. Product names such as Anacin (long recognized as a combination of aspirin and caffeine), Bayer (aspirin), Benadryl (diphenhydramine), and Chlortrimeton (chlorphenaramine) are now being marketed over combinations of ingredients that contain no aspirin and caffeine (Anacin-Free), no aspirin (Bayer Select), no diphenhydramine (Benadryl cough syrups), and no chlorphenaramine (Chlortrimeton Non-Drowsiness Formula). This practice causes substantial confusion among consumers and pharmacists that is not in the best interest of good self-medication.

The House of Delegates has directed MPhA to take several steps to attempt to resolve this problem. Those steps include filing formal requests for review with the FDA, USP, Federal Trade Commission, APhA and NARD. More importantly, the House needs help from all MPhA members!

If you come across an example of a confusing OTC product label, send the name or the product and a photocopy of the packaging to the MPhA offices. This information will be used to file our complaints with the agencies listed above. You can mail your examples or, if you prefer, FAX them to MPhA at (410) 727-2253.



1995 Award Recipients

Each year, MPhA recognizes and honors outstanding Maryland pharmacists. This year, outgoing President **Arnold Davidov** presented the following awards at the 113th Annual Convention Banquet on Tuesday, June 20, 1995 at the Sheraton Ocean City Resort Hotel:

The *Seidman Distinguished Achievement Award* was established in 1980 to honor the major impact on Maryland pharmacy by Henry Seidman. The award is presented for outstanding service by a Maryland pharmacist to the pharmacy profession during *either* the past year or over a period of years. The recipient receives a plaque and clock. This year's selected pharmacist is **Ralph Shangraw**, long-time professor of pharmaceutics at the University of Maryland School of Pharmacy.

The *MPhA Honorary President* is an honorary position on the Board of Trustees given to a person who has worked for the MPhA or Maryland pharmacy over a long period of time. The 1995-1996 Honorary President is **Maribeth Porter**, who recently left the MPhA staff after six years as Office Manager.

The *Wyeth-Ayerst Bowl of Hygiea Award* recognizes a pharmacist who has performed outstanding services to the community in any area, with a particular emphasis on non-pharmacy contributions. The recipient receives a plaque, a lapel pin, and a trip to meet with other Bowl of Hygiea recipients. **R. Dennis Hager**, mayor of Millington in Kent County, was presented with the Bowl of Hygiea by Wyeth-Ayerst's Ray Langston.

The *Marion Merrell Dow Distinguished Young Pharmacist Award* is given to a pharmacist who has graduated within the past nine years and has made a significant contribution to the profession through service in a local, state, or national pharmacy organization. **Mark Sanford**, MPhA's Speaker of the House of Delegates, received the award from Marion Merrell Dow's Sabina Casazza.

Created in 1993, the *Dupont Innovative Practice Award* recognizes forward-thinking pharmacists who have expanded their practices into new areas. This includes adding a new service, restructuring a pharmacy and its current services, or developing a completely new practice. The award recipient receives a plaque, a medal, and a framed water-color sketch. Montgomery County pharmacist **Irwin Rosenberg** was recognized for his development of a substantial niche-market in nutritional care.

Always Double Check

Look-alike and sound-alike drug names can be misread or misinterpreted by a nurse reading doctors' orders or by a pharmacist dispensing physicians' prescriptions. Such misunderstandings can result in the administration of a drug not intended by the prescriber. Awareness of such look-alike and sound-alike drug names can reduce potential errors.

| | | |
|---------------|---------------------|----------------------|
| | <u>Proloprim</u> | <u>Protropin</u> |
| Category: | Antiinfective | Growth hormone |
| Manufacturer: | Wellcome | Genentech |
| Generic Name: | Trimethoprim | Somatrem |
| Dosage Form: | Tablets | Powder for injection |
| | | |
| | <u>Dipyridamole</u> | <u>Disopyramide</u> |
| Category: | Antianginal | Antiarrhythmic |
| agent | | |
| Generic Name: | Dipyridamole | Disopyramide |
| Dosage Forms: | Tablets | Capsules |

Contributed by Benjamin Telplitsky, R.Ph.

Alumni Association Honors

Steven Cohen, Vice President of Operational Development for Helix Health System, has been selected as this year's Honored Alumnus by the Alumni Association of the School of Pharmacy at the University of Maryland at Baltimore (UMAB). Cohen is currently completing his tenth year as a member of the Maryland Board of Pharmacy, eight as its president. Cohen received his award at the Alumni Association's annual Spring Graduation Banquet on May 18th at the Hunt Valley Marriott.

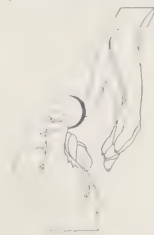
During the Annual Banquet, **Ellen Yankellow** was installed as President of the Alumni Association. Yankellow is employed by Choice Drug Systems of Maryland as Vice President of Pharmacy Operations. She is just completing her term as president of the Baltimore Metropolitan Pharmacists Association (BMPA) and was a former MPhA trustee.

Rounding out the 1995-96 Alumni Association's leadership are: **Alisa Billington, Dixie Leikach, Abigail Lagman, Ronald Sanford, Lynette Bradley, Jean Dinwiddie, George Garmer, Kathy Gauthier, Henry Leikach, Charles Sandler, Mark Sanford, and Ernest Testerman.** The Honorary President is **Jacquelyn Lucy**, former staff to the Alumni Association who has retired from the University of Maryland School of Pharmacy to pursue her own business as a marketer and promotions manager for small-businesses.



Resist Temptation

It sounds reasonable. For every patient you refer to a certain durable medical equipment dealer, they'll pay you the equivalent of one month's rental on any equipment or supplies obtained by that patient. Considering the high investment in inventory and specialized training and personnel necessary to serve DME needs, it sure seems like a great -- and profitable -- alternative to doing it yourself.



Trouble is, payment for referrals are illegal. Last August, the Department of Health and Human Services' Office of Inspector General issued a "Special Fraud Alert" that reminded providers about the Medicare and Medicaid Anti-Kickback Law. Violators are subject to criminal penalties or

exclusion from participation in the Medicare and/or Medicaid programs. Among its provisions, the anti-kickback statute penalizes anyone who knowingly and willfully solicits, receives, offers or pays remuneration in cash or kind to induce or in return for:

- referring an individual to a person for the furnishing or arranging for the furnishing, of any item or service payable under the Medicare or Medicaid program; or
- purchasing, leasing or ordering, or arranging for or recommending purchasing, leasing or ordering, any good, facility, service, or item payable under the Medicare or Medicaid program.

When investigating potential improprieties, the Office of Inspector General looks for payments or gifts which are:

- Made to a person in a position to generate business for the paying party;
- Relate to the volume of business generated; and,
- More than the nominal in value and/or exceeds fair market value of any legitimate service rendered to the payer, or is unrelated to any service at all other than referral of patients.

Three CE....

credits that is! Michael Heinzman, MPhA's Purdue Frederick representative, is offering all MPhA members a three-credit monograph entitled "Asthma - A Nocturnal Disease."

To obtain your copy, call Mike at (800) 745-7445, extension 644004. Leave your name, mailing address, city, state and zipcode on his voicemail and he will mail you a copy of the 50 page booklet.

Health Insurance Rates

If you're about to change your personal or employee's health insurance carrier, you probably want to take a look at the series of rate guides produced by the Maryland Insurance Administration.

The guides, which separately cover four geographical regions in Maryland, explain the state's comprehensive standard health benefit plan and provide rate information for almost 80 different indemnity, HMO, PPO and POS plans. For free copies of the "Insurance Rate Guide" contact the Maryland Insurance Administration at (410) 333-8209.

Aging Assistance Available

MPhA is one of the founding participants of SeniorReach, a program coordinated by the State's

Office of Aging. SeniorReach has developed a number of consumer education materials for aging Marylanders and their caregivers. These include:

- "Abuse is Wrong at Any Age" brochure. This pamphlet highlights signs of abuse and services that are available for abuse victims, their family members, or those at risk of being abused.
- "Guide to Managed Care for Medicare Beneficiaries" booklet. This booklet explains the concept of managed care for people with Medicare. Features of managed care are described and information regarding specific Medicare managed care options offered in Maryland are presented.
- "ElderCare Locator" brochure. This document highlights information about the nationwide directory assistance service for older people and caregivers. The service links callers with the information and referral networks of state and local area agencies on aging.

For single or bulk copies of these materials, call Susan Collier, Maryland Office on Aging, at (410) 225-1270.



National Pharmacy Week

America's pharmacists are plunging into the future of healthcare reform with a solid vision for the pharmacy profession -- a vision of pharmacists as patient care managers, integral to successful healthcare management.

To publicize pharmacists expanding roles,

APhA is again coordinating the annual National Pharmacy Week, October 22-28, 1995. The week-long observation concludes the annual Talk About Prescriptions Month.

APhA members can order a free planning guide chock-full of National Pharmacy Week promotional materials by writing to APhA's promotions company, Trexco, 1251 Gordon Park Road, Augusta, GA 30901. Non-members should send a check for \$5, payable to Trexco.



**National Pharmacy Week
October 22-28, 1995**

ASCP Regional Meeting

The Maryland State Chapter of the American Society of Consultant Pharmacists is holding its second annual Mid-Atlantic Conference starting Friday, August 4th through Sunday, August 6th at the Radisson Lord Baltimore Hotel in Baltimore.

The educational goal of the conference is to provide pharmacists with the skills and information that will help them seize emerging opportunities in long term care practice. The program will offer up to 17 CE credits in a wide range of topics, including the basics of Drug Regimen Review, regulatory issues on both state and national levels, outcome assessments, disease management, and specific disease states applicable to any practice setting.

The conference will feature exhibits from corporate sponsors displaying new technologies and medications. Social events include a Friday evening dinner and CE program, a Saturday evening reception and a traditional Maryland Crab Feast on Baltimore's world famous Inner Harbor! The program will close with a luncheon and CE program Sunday afternoon.

MPhA has assisted the ASCP-Maryland chapter in coordinating the program. All MPhA members should have received a blue and white program guide and registration materials in June. For details, or additional information on the program and registration, call MPhA's Director of DUR Services Richard Baylis at (410) 727-6122.

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October 7-11, 1995
Las Vegas, Nevada

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| <input type="radio"/> Golf Tournament | \$140 |
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5. Payment:

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My grand total is: _____

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☐ Charge my:

☐ American Express ☐ MasterCard ☐ Visa

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Signature _____

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☐ Team Member—Registration fees paid by:

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Member #

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We will not reserve housing without a paid convention registration.

Please read all instructions before completing the housing application.

Hotel reservations can be made through the NARD Housing Bureau only.

Reservations will be processed on a first-come, first-served basis. To secure a room, reservations must be received prior to September 1, 1995. After this date, requests will be handled on a space-available basis. A deposit equal to one night's stay is required to hold each reservation.

NARD will acknowledge receipt of your reservation by mail. This is NOT a confirmation. A confirmation will be forwarded directly by the hotel (please allow four weeks). Changes in arrival/departure dates, accommodations, and cancellations are to be made through the NARD Housing Bureau. After September 1, 1995, notify the hotel directly.

Refunds will be made only when cancellations are received at least 48 hours prior to scheduled arrival date.

1. Participating Hotels and Rates

Check box next to your first choice.

Hotel

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| <input type="radio"/> Las Vegas Hilton (casino) | \$119 |
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| <input type="radio"/> Alexis Park Suites (non-casino) | \$125 |
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2.

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| Name | _____ |
| Sharing room with | _____ |
| Arrival Date | _____ |
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| Number in Party | _____ |

3. Special Requests:

- ☐ Non-smoking, if available
- ☐ Low floor

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Signature _____

MARYLAND

BOOK EARLY! AFTER SEPTEMBER 1, 1995, THE AVAILABILITY OF ROOMS AND RATES CANNOT BE GUARANTEED.

Criminal Background Checks

Part 2

As reported in last month's newsletter, the Maryland State Board of Pharmacy is under pressure from legislative auditors to conduct regular criminal background checks on all new and current license and permit applicants.

MPhA's leadership is concerned that all pharmacists' professional reputation be protected in light of the over-zealous demands of the legislative auditors. MPhA has formally requested that the Board of Pharmacy cease all activities in this area until formal policies and procedures for handling the background data and results of the checks -- including subsequent investigation of pharmacists -- are developed and published. Currently, no such policies exist. However, the responsibility to conduct these background checks still remains with the Board.

The Board plans to use your Social Security number to conduct the criminal background checks through the Department of Public Safety and Correctional Services. They obtain this information from your license renewal form.

Please note: you are not legally required to provide your Social Security number to the Board. Nor do you have to provide race information or your birthdate.



Post Scripts

- R Upjohn has announced receipt of FDA approval for Caverject (alprostadil), an injectable for the diagnosis and treatment of erectile dysfunction. It is the first prescription medication for male impotence treatment cleared for marketing by the FDA. Impotence affects an estimated one in ten, or between ten to 20 million men, in the United States.
- R In a deal that will boost their penetration by an estimated \$145 million in sales, Rite Aid has purchased the entire chain of conventional freestanding drugstores owned and operated by Pathmark Stores. The 30 Pathmark pharmacies are concentrated in metropolitan New York.
- R SmithKline Beecham has received clearance to market Tagamet HB, an OTC version of its popular cimetidine product. Available in early fall, Tagamet HB dosing is two 100 mg tablets taken up to twice a day for relief of heartburn. Prescription-strength Tagamet will remain available.
- R Forest has introduced Cervidil (dinoprostone 10mg), the first controlled-release vaginal insert for initiating and/or continuing cervical ripening in pregnant women at or near term who have a medical or obstetrical indication for the induction of labor. Cervical ripeners are needed in 10 to 11 percent of pregnancies.
- R The FDA has approved a reduction in the frequency of liver monitoring in patients treated with Warner-Lambert's Alzheimer's drug Cognex (tacrine). This change will reduce the frequency of blood tests by more than half, from up to 24 times to 10 for the first six months of treatment. Approval was based upon data from 276 patients monitored every other week, and compared with 6,500 patients monitored weekly in clinical studies and in the Cognex Treatment IND.
- R By now you've probably seen the consumer demand for Pepcid AC, Merck's 10mg OTC version of famotidine. Accompanied by extensive marketing campaigns, Pepcid AC is available in packages of 6, 12, and 18 tablets.
- R CibaGeneva has published a "report card" on managed care plans called the *CibaGeneva Pharmacy Benefit Report: Trends and Forecasts*. The 1995 edition highlights important pharmacy program design trends and initiatives. Based on surveys of HMO pharmacy directors and employee benefit managers, *Trends and Forecasts* provides unique information on HMO pharmacy program design characteristics. To order a copy of the booklet, call CibaGeneva at (800) 475-2273.

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Telephone numbers are provided for additional information and promotional materials.

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Sickle Cell Month (800) 421-8453

October

Breast Cancer Awareness Month . (212) 382-2169

Lupus Awareness Month (800) 558-0121

Liver Awareness Month (201) 256-2550

SIDS Awareness Month (800) 221-7437

Talk About Rx Month (202) 347-6711

Pharmacy Week, 10/22-28 (800) 237-2742

MPhA Hosts Conference

Each summer, the Southeastern Pharmacy Associations meet to discuss issues that affect our members. Topics range from organizational structure to new member benefits and services. The purpose of the meeting is to develop stronger regional ties and to share winning strategies that improve the services pharmacy associations provide to members.

This year, MPhA is hosting the July conference at the Loews Annapolis Hotel. Your officers and staff plan to meet with the leaders of state pharmacist organizations from Alabama, Mississippi, Louisiana, Florida, Georgia, Virginia, Tennessee, and North and South Carolina.



Maryland Pharmacy Event Calendar

Aug 4-6 ASCP Mid-Atlantic Regional Meeting, Radisson Hotel, Baltimore. Call (410) 727-6122.

Aug 13 Washington County Seminar and Picnic. Call Chris Brown at (301) 739-2780.

Sept 18-23 NARD OTC Health Support and Appliance Fitting School and Examination, Dallas, TX. Call (800) 544-7447.

Oct 8-11 NARD Annual Convention, Las Vegas, NV. Call (800) 544-7447 and see enclosed brochure.

Oct 20-21 MSHP Annual Seminar, Sheraton Society Hill Hotel, Philadelphia, PA.

Oct 20-22 APhA-Academy of Students of Pharmacy Regional Meeting, Baltimore. Call (800) 237-APhA.

Oct 28 BMPA Annual Dinner Dance and Awards Banquet, Sheraton Towson

Dec 13-17 ACA Specialty Training Program in Respiratory Diseases. Call (703) 684-8603.

1996

Feb 25 MPhA Mid-Year Meeting, Loews Annapolis Hotel, Annapolis, Maryland.

March 10 AZO Fritz Berman Memorial Seminar, "Diseases of the Eye"

NEWSLETTER

The Maryland Pharmacists Association

650 Lombard Street

Baltimore, Maryland 21201



MARYLAND PHARMACIST

July, 1995

Vol. 71, No. 7

- Satisfied Women
- Board Report
- New PEP for Students
- Added Refills
- Interactions
- CE: More New Drugs



1995-1996 MPhA President
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MARYLAND PHARMACIST

The Official Publication of The Maryland Pharmacists Association

July 1995

4 President's Commentary

Newly installed President Jim Tristani presents his first Commentary on commitment and long-term relationships.

5 Women in Pharmacy

The impressions and impact of female pharmacists is the focus of the 17th Annual Schering Report. Schering's Pharmacy Affairs Jack Robbins gives MPhA an exclusive first-look at the results of the report.

10 Annual Report of the Maryland Board of Pharmacy

Board Secretary and Commissioner Melvin Rubin presents the formal report of our profession's licensure Board to the pharmacy community.

18 Litigation Update

Whose responsible when a patient adds refills to a prescription? The answer may surprise you when columnist David Brushwood looks at another pharmacy case.

19 Bridging Education and Practice

Faculty members Stuart Haines and Magaly R. deBittner explain how the Pharm.D. curriculum is bringing an expansion and redesign of the School's experiential program.

22 Continuing Education

This month, we return to our review of new drug products with an analysis of aprotinin, calcipotriene, and stavudine. Don't forget the CE quiz on page 30 for credit! It's free for all MPhA members and credits are now ACPE approved.

28 Interactions

Ensuring free and open access, regardless of backgrounds, is a positive challenge for the School and the profession. Dean David Knapp looks at who the School is meeting this challenge.

The Maryland Pharmacist (ISSN 0025-4347, USPS 332-040) is published monthly by the Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201-1572. Annual subscription - \$10. Single issue copy, \$1.50. Members of the Maryland Pharmacists Association receive the publication as part of their annual membership dues. Entered as second class matter at Baltimore, Maryland and additional mailing offices.

Articles and editorials that appear do not necessarily reflect the official positions of the Maryland Pharmacists Association and may contain views and opinions for which the authors hold sole responsibility.

Postmaster: Send address changes to MPhA, 650 West Lombard Street, Baltimore MD 21201.

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Whenever the opportunity arises, please thank them for their support.

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President's Commentary

On Relationships and Commitment

Ask the typical pharmacist what he or she thinks is the biggest problem in pharmacy and they'll probably respond "third-parties." Even the most optimistic pharmacist is frustrated about the continued decline in reimbursement and, even more importantly, the depersonalization of the patient/pharmacist relationship by prescription benefit managers whose first loyalty is to the company paying the bills. It seems to me that most third-parties think that relationships are meaningless -- only the bottom line is of any concern.

It's not just third-parties who are guilty of disrupting pharmacist/patient relationships. Employers who are understandably trying to control their health care costs often overlook established connections between employees and their health care providers. And, yes, even we pharmacists are guilty of taking our relationships for granted. Think about all those patients you *didn't* counsel or chat with when you knew they wanted to talk. Think about those patients you hurried along because you were in a rush to get back to that next prescription or that next telephone call. Sadly, damaged relationships are harder to repair than they are to maintain.

It may surprise you to know that the Association is in the same position as you are! Just as you're doing more with *and for* a heck of a lot less, so it seems are we. We're also continually working on relationships with our current members, trying to establish relationships with non-members, communicating and cooperating with groups like the Maryland Association of Chain Drug Stores, the Maryland Society of Health-System Pharmacists, our local affiliates, and many, many more. Certainly one of the most important relationships we have is with our colleagues in the pharmaceutical industry.

Unfortunately, some of our industry relationships are deteriorating. Many of our long-time supporters were conspicuously absent from the 113th Annual Convention. They didn't exhibit. They didn't contribute. They didn't attend. Many expressed regret that "due to reorganization" or "budget reductions" they just weren't able to be there for us this year. But, to me, those are excuses as hollow as the ones we make to ourselves when we run back to our computer and ignore a real-live patient depending on us.



James Tristani, P.D.
1995-96 MPhA President

Major companies like Glaxo, Novo Nordisk, Searle, and Upjohn were there in strong support of our Convention. Bristol-Myers Squibb is coordinating an AIDS education program with us for the fall. Our friends at Schering provided several expensive advertisements for this magazine earlier this spring. Other companies like Becton-Dickinson, Astra/Merck, Schein, CibaGeneva, Boots, and Procter & Gamble are also strong allies and friends of MPhA. I can't begin to tell you enough how much I and you should appreciate their commitment to MPhA. Those are relationships we must cultivate and maintain.

But some major companies whose goods we dispense many times a day are just plain *missing* absent from MPhA activities. I can only hope that they will let us know what we can do to re-establish a good, cooperative working relationship. The door is always open to talk.

PS. As this is my first "Commentary" to the Association members, I wanted you to know that I want to use this column as a forum in the coming months to bring about discussion from members and non-members on trends and problems that affect pharmacists. I encourage you to respond to my comments or suggest topics which you would like to see included in future issues and articles. Please feel free to call or write the Association's offices at any time for assistance.

Women In Pharmacy

The Results of The 17th Annual Schering Report

Jack Robbins, Ph.D.

Director, Pharmacy Affairs, Schering Laboratories

Female pharmacists -- now comprising one-third of the working profession -- are significantly more satisfied than male pharmacists with their choice of career, less concerned about managed health care and other challenges, and far surer that their growing numbers will benefit the profession.

These were among the major finds of a new, independent survey of pharmacists' attitudes commissioned by Schering Laboratories.

Nine out of 10 pharmacists, both men and women, report that they are satisfied with pharmacy as a profession, but more women (51 percent) than men (35 percent) say they are *completely* satisfied with the pharmacy profession. That's a substantial difference.

On managed health care issues, almost two-thirds of the pharmacists surveyed reported that they were affiliated with a managed care organization. Women evaluated the business impact of their affiliations much more favorably than men. About two-thirds (64 percent) of women but only (43 percent) of men believe that a managed care affiliation was beneficial. Conversely, only 11 percent of female pharmacists compared with 35 percent of male pharmacists thought managed care had an adverse impact.

Schering Report XVII -- Women in Pharmacy: A New Complexion for the Profession -- proved three major issues confronting pharmacy: the role of women in the profession; the impact of managed health care on pharmacy practice; and the potential implications for pharmacy of universal health care coverage.

The study was based on 400 interviews with pharmacists across the continental United States. Interviewers questioned equal numbers of men and women, including owner/managers and staff pharmacists working in independent and chain drug stores, supermarket and department store pharmacies, hospitals and health maintenance organizations (HMO).

Female Domination?

Until World War II, pharmacists, like physicians, were predominantly men. By 1972, almost a quarter-century later, barely 13 percent of employed pharmacists were women. In 1994, though, women comprised 38 percent of working pharmacists. That level is certain to rise since almost two-thirds of all current pharmacy students and recent graduates are female. If this trend continues, the year 2000 may well usher in the "Century of Women" in pharmacy. It takes only a sideward glance at other medical profession to see how far women have come in pharmacy. Only one in five physicians is a women. In dentistry, women are a mere one in 12.

The Schering Report revealed pharmacists as a group almost evenly divided (45 percent to 46 percent) on whether more women in pharmacy will have a positive effect on the profession or make no difference at all. Only eight percent said it would have a negative influence.

Not unexpectedly, female pharmacists were twice as likely as their male colleagues (63 percent to 30 percent) to believe that good things will flow from the feminizing of pharmacy.

Pharmacists expressing a positive view said that women tend to be more caring, understanding and sensitive; have good rapport with patients; and are better organized and patient. Pharmacists who voiced a neutral opinion maintained that gender is irrelevant as long as the job gets done, that the education and training of men and women are equivalent, and that women are accepted in all professions.

In a minority role, pharmacists with a negative view claim that women tend to lower the salary base of the profession, look for part-time work, and place family interest first during child-bearing years.

Asked why they chose pharmacy as a career women and men cited similar reasons -- altruism or service to society; interest in science and medicine; a desire for a secure, well-paying, interesting career; and family and childhood influences.

Service was the first priority for most women and men. Nearly 25 percent of both groups said they like helping people, and that's what pharmacy is all about. Next came an interest in science in general or in a medical profession, specifically, with each reason cited about 20 percent of both women and men.



Job security and good paychecks taken together were cited by a quarter of women and men. However, they weighed each reason differently. Fifteen percent of men but only about 10 percent of women indicated that they were motivated by the opportunity for a secure career. Conversely, 16 percent of women versus 9 percent of men mentioned a "good salary" as a reason for their career choice. About 10 percent of both women and men said they were attracted to pharmacy because it was an interesting and challenging career.

Family tradition and influence were also important factors in career choice. Ten percent of both genders said pharmacy was a family tradition, about the same proportion was influenced by friends. A good one-third of all respondents had a pharmacist in the family, and almost one in 10 pharmacists is married to another pharmacist.

So, Who's Where?

The Schering Report identified chain pharmacy as a primary gateway to a pharmacy career for women. Nearly one-half (47 percent) of recent female graduates were employed in chain store pharmacies. This was four times the number in independent or department store pharmacies, and five times the number in hospital or HMO pharmacies. Women outnumber men in chain store pharmacies by a 10-point margin (38 percent to 28 percent).

Women pharmacists also reported working in bigger and busier pharmacies that fill on average 250 prescriptions per day, in contrast to the daily average of about 170 prescriptions, as reported by men. Better than half (53 percent) of women work in pharmacies with three or more pharmacists, while only about one-third (35 percent) of men work in such busy pharmacies. Both finds reflect the greater

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employment of women in chain pharmacies, the study noted. Working in high-volume pharmacies -- with few management responsibilities -- women fill more prescriptions daily than men, an average of 105 to 93.

The Schering Report also probed the issue of pharmacy management. As the historic majority in pharmacy, men naturally have about twice as much experience as women. This fact might partially explain the minority presence of women in management.

While pharmacy management still appears to be a male turf, it probably won't be for long. Male pharmacists currently predominate as owners, managers or directors by a 27-point margin (53 percent to 36 percent). Women's status is a mirror image, with nearly two-thirds (63 percent) remaining staff employees compared with slightly more than one-third (37 percent) of men.

Views on Managed Care

On managed care issues, pharmacists said that about 60 percent of their prescriptions are third-party or co-pay. Some 64 percent of pharmacists were affiliated with a managed care organization. The percentage was less for hospital pharmacies (48 percent) and mass-merchandisers (55 percent), but

almost total for HMOs (96 percent). Of pharmacists reporting a managed care affiliation, over half believed that participation had been good for their business, 23 percent held opposing views, and 20 percent could see no significant effect on their pharmacy income.

Pharmacists are not ardent fans of managed care, the study concluded. Fully one-third of the respondents could see no advantages to pharmacists in its growth, while only 13 percent saw no disadvantages. The study also found that pharmacists with an opinion on managed care took a bleak view of universal health care. On nine of the 10 aspects of pharmacy surveyed, negative expectations far outweighed positive views.

Even the otherwise pervasive female optimism was pretty much absent on this issue. Female pharmacists were "gentler and kinder" toward universal health care, but by only a few percentage points.

Summary

Despite all their concerns and doubts, pharmacists are overwhelmingly satisfied with pharmacy as a profession. The acid test of satisfaction with the profession may well be whether pharmacists want their sons and daughters to follow their career paths.

Asked if they would want their children to follow them into the profession -- a key measure of career satisfaction -- eight of 10 female pharmacists and nearly two-thirds of male pharmacists said they would

want a daughter to become a pharmacist. Significantly, 74 percent of female pharmacists and only 54 percent of male pharmacists wanted a son to follow their career pathway.

The message is clear. Both genders in pharmacy sense that -- in the future -- the profession may be more rewarding to women than to men. The higher levels of male dissatisfaction and pessimism on many counts lend support to this conclusion. **MP**

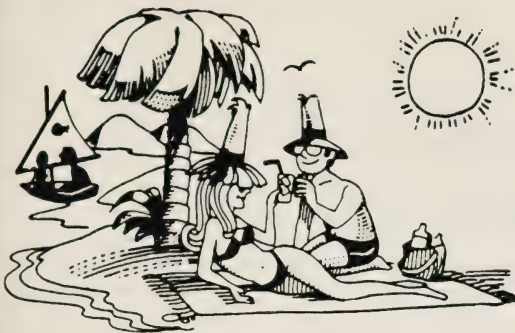
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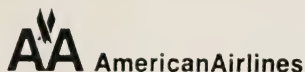
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MPA

Annual Report of The Maryland State Board of Pharmacy

*Melvin N. Rubin, P.D., Secretary and Commissioner
Maryland State Board of Pharmacy*

in compliance with the provisions set forth in the Health Occupations Article 12-205 of the Annotated Code of Maryland, this report is submitted to the Honorable Parris N. Glendening, Governor

of Maryland, the Secretary of Department of Health and Mental Hygiene, Martin P. Wasserman M.D., J.D., and to the Maryland Pharmacists Association. This is the ninety-second report to the Governor and Secretary and the thirteenth report to the Association. The report covers the activities of the Maryland Board of Pharmacy for the period May 1, 1994 to April 30, 1995. This report is also being submitted to the McKeldin Library of the University of Maryland, the Enoch Pratt Free Library, the Department of Legislative Reference, the Hall of Records and the State Library.

Meetings

During the year, the Board held seventeen meetings, five of which were held at the School of Pharmacy of the University of Maryland, for the purpose of conducting examinations for licensure of pharmacists.

Officers and Members

The Board consists of the following officers and commissioners: Steven S. Cohen, President; Melvin N. Rubin, Secretary; Barbara J. Faltz Jackson, Robert J. Kabik, Dorothy Levi, Theodore S. Litwin, George Voxakis, David Russo. All of the officers and commissioners are registered pharmacists in the State of Maryland with the exception of Mr. Litwin and Ms. Jackson who are consumer (public) members of the Board.

Personnel

The staff consists of: Norene Pease, Executive Director; Tracy Baroni, Pharmacist Compliance Officer; Tamarra Banks, Administrative Officers; Lenora Williams, Secretary to the Executive Director; David Oliver, Secretary to the Pharmacist Compliance Officer; Shawnette Fleet, Licensing Secretary; and Doris Thomas, Fiscal Aide.

Examination

The Board conducted examinations for licensure of pharmacists during the year. They were held at the University of Maryland School of Pharmacy on June 28, 29 and 30 1994 and September 27 and 28, 1994. The

applicants who were examined in June 1994 were licensed in July, 1994, which is in FY 1995. There were one hundred seventy-three applicants for the Board examination in June 1994. One hundred fifty-nine passed both the theoretical and practical portions of the examination and were licensed. Fourteen failed the examination. There were forty-eight applicants for the Board examination in September, 1994 (FY 1995). Forty passed both the theoretical and practical portions of the examination and were licensed. Eight failed the examination. Data relative to the June 1995 examination will be given in the next Annual report.

The pharmacist licensure examination is given in three parts consisting of the following: Part I -- NABPLEX, Part II -- Pharmacy Law, Part III -- Laboratory. The NABPLEX is obtained from the National Association of Boards of Pharmacy. The Pharmacy Law Exam and the Laboratory Exam are compiled by members of the Board. There has been a change in the law portion, the change means that examinees will not be concerned about whether a question relates to a Federal mandate or the State law. Answers must relate to what a pharmacist in Maryland does to comply with the law. The Laboratory Examination requires the compounding of four prescriptions per applicant. Each of the three parts will stand on their own. An examinee need only retake the section(s) failed. The passing grade for each section is 75 percent.

Table One shows the numbers of pharmacists who were licensed by examination during the past ten years.

As in the past, many pharmacists applied for reciprocal licensure in Maryland in order to accept positions with their employers in Maryland. In all cases, an applicant for reciprocal licensure must appear for a personal interview. The entire Board must act on whether or not to grant licensure to such applicants, who must sign an agreement to comply with Maryland's laws pertaining to drugs and pharmacy.

Table Two table shows the number of pharmacists granted licensure by reciprocity and the number who were certified to be licensed by reciprocity in other states during the past ten years.

Permits

As of April 30, 1995, two hundred eight-seven (287) new permits to operate a pharmacy were issued. These pharmacies were located in the following counties: Anne Arundel (5), Baltimore (5), Baltimore City (12), Carroll (2), Frederick (2), Harford (2), Howard (3), Montgomery (6), Prince Georges (10), St. Mary's (2), Talbot (1), Washington (4).

In June, 1987, regulations were promulgated under COMAR, Title 10, Subtitle 34, Chapter 17, allowing waiver of full service requirements for recognized pharmaceutical specialties. As of April 30, 1995, the Board issued eighteen (18) new pharmacy waiver permits as follows: Baltimore County (5), Anne Arundel County (1), Howard County (3), Montgomery County (2), Prince Georges County (1), Wicomico County (1), Allegheny County (1), Garrett County (1), Frederick County (1), Baltimore City (2).

New permits to manufacture drugs, medicines, toilet articles,

dentrifices or cosmetics as of April 30, 1995 were issued to three firms. The Board issued eighty-eight (88) new permits to distribute prescription drugs as of April 30, 1995. The total number of establishments licensed through the State of

Pharmacists Licensed By Examination

| Year | Pharmacists |
|---------|-------------|
| 1983-84 | 92 |
| 1984-85 | 92 |
| 1985-86 | 109 |
| 1986-87 | 105 |
| 1987-88 | 121 |
| 1988-89 | 135 |
| 1989-90 | 167 |
| 1990-91 | 156 |
| 1991-92 | 149 |
| 1992-93 | 145 |
| 1993-94 | 199 |
| 1994-95 | 199 |

Table 1

Maryland is **1,382** and the total number of pharmacists is **6,570** as of April 30, 1995.

Legislation

The following bills which affect pharmacy either directly or indirectly were enacted by the 1995 General Assembly. These bills must be signed by the Governor to become effective.

SB 329 Pharmacy Rehabilitation Committee/Funding

This bill provides enabling legislation for the Board of Pharmacy to allocate funds from the special fund to the Pharmacist Rehabilitation Committee for the purpose of providing drug and alcohol prevention treatment to pharmacists identifying themselves as needing such services.

SB 446/HB 1199 Home Medical Equipment Providers

This bill authorizes the Board of Pharmacy to license and regulate home medical equipment providers. The bill was defeated in the Senate and HB 1199 has been referred to summer study.

Pharmacists Licensed By Reciprocity and Certification

| Year | Reciprocity | Certification |
|--------------|--------------|---------------|
| 1983-84 | 119 | 58 |
| 1984-85 | 148 | 54 |
| 1985-86 | 191 | 70 |
| 1986-87 | 206 | 75 |
| 1987-88 | 197 | 57 |
| 1988-89 | 228 | 86 |
| 1989-90 | 187 | 103 |
| 1990-91 | 212 | 98 |
| 1991-92 | 178 | 86 |
| 1992-93 | 192 | 119 |
| 1993-94 | 190 | 88 |
| 1994-95 | 183 | 52 |
| Total | 2,231 | 958 |

Table 2

Cooperative Activities

The Board maintained cooperative activities with the Division of Drug Control, Licensing and Certification, the State Department of Health and Mental Hygiene, the University of Maryland - School of Pharmacy, the Maryland Pharmacists Association, the Maryland Society of Health-System Pharmacists, the Maryland Association of Chain Drug Stores, Maryland Society of Consultant Pharmacists, City, County and State Police, the National Association of Boards of Pharmacy, and all pharmacy boards and schools throughout the country.

Disciplinary Activities

The Board of Pharmacy receives complaints from the public concerning problems with the Board's licensees. Other complaints were received from the Division of Drug Control, Medical Assistance Compliance Administration, Licensing and Certification, State of Maryland Courts, and other state boards of

pharmacy. The wide range of complaints varied in severity. Listed in Table Three are statistics concerning the types of complaints for the period of May 1994 through April 1995.

During the period of FY 1995, eighteen orders were issued and distributed for public information. These 18 orders regarding 17 pharmacists and one pharmacy, which included:

Pharmacists

| | |
|---|---|
| Emergency suspension | 1 |
| Suspensions with immediate stay and probation | 6 |
| Full reinstatement | 8 |
| Surrender of license | 1 |
| Revocation | 1 |

Pharmacy

| | |
|--------------------------------|---|
| Emergency suspension | 1 |
|--------------------------------|---|

During this period, the Board voted charges for violation of pharmacy law against 22 pharmacists and one pharmacy. Eighteen of the 23 cases have been concluded (included in the above statistics) and five are outstanding. The Board has four additional outstanding cases from the previous year which have not been concluded. Of these, three pharmacists' licenses are currently suspended on an emergency basis pending final resolution. The Board has voted charges for formal action against the one remaining case.

Some pharmacists were convicted of violating more than one provision of the Pharmacy Practice Act. Listed below are the types of violations according to the section of 12-313 (b) of the Health Occupations Article and the numbers of pharmacists convicted of each.

(4) Provides professional services while: (i) Under the influence of alcohol; or (ii) Using any narcotic or controlled dangerous substance, as defined in Article 27 of the Code, or other drug that is in excess of therapeutic amounts or without valid medical indication; **One Convicted**

(14) Without first having received a written or oral prescription for the drug from an authorized prescriber, dispenses any drug for which a prescription is required; **Two Convicted**

(20) Is professionally, physically, or mentally incompetent; **Two Convicted**

Complaints Against Pharmacists

| | |
|---|----|
| Mislabeled prescriptions | 3 |
| Incorrect drug dispensed | 32 |
| Shortages of controlled drugs | 3 |
| Communication | 3 |
| Dispensing habits of pharmacist | 5 |
| Fraud | 2 |
| Prescription not dispensed | 4 |
| Theft of drugs | 1 |
| Board action by another State | 1 |
| Inconsistent with professional standard | 12 |
| Continuing education | 7 |
| Duties of technician | 1 |
| Moral character | 1 |
| Impaired/chemical dependency | 2 |
| Total Complaints | 77 |

Table 3

*The Right
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(21) Is convicted of or pleads guilty or nolo contendere to a felony or to a crime involving moral turpitude, whether or not any appeal or other proceeding is pending to have the conviction or plea set aside; **Two Convicted**

(23) Is disciplined by a licensing or disciplinary authority of any other state or country or convicted or disciplined by a court of any state or country for an act that would be grounds for disciplinary action under the Board's disciplinary statutes;

One Convicted

Operations

The Board of Pharmacy's five year office automation plans were developed in fiscal year 1993 and are expected to be completed on schedule. A key feature in the plan was the installation of the Board's computer network, the personal computer link for each Pharmacy Board staff member. The network has been operating at 98% reliability since March 1994. The legislative audit performed during this period tested the accuracy and efficiency of the Board's newly developed and implemented computerized logs. Information could be provided to the auditors quickly, and with the exception of a few minor details, proved to be completely consistent with State guidelines. The new automation system incorporates financial management, audit trails, information retention periods, storage and usage of controlled items such as licenses and certificates and separation of duties. The public perceives faster responses to inquiries because more information is available to Board staff. The Board expects to see more improvements in the way in which the public is served.

As a result of the passage of Senate Bill 655 the Board of Pharmacy became special funded effective July 1, 1992. All revenues collected by the Board are used to cover the costs of operation. Fiscal year 1994 marked the first year that the Board could accurately predict its revenues and operating costs. Initially, the pharmacist licensure fee was established at \$130 to be paid every two years. Although the fee was established to be commensurate with licensure fees in other states, revenues for FY 1993 and 1994 significantly exceeded expenditures. As a result, the pharmacist licensure fee was reduced to \$95 to be paid every two years. The adjusted fee has had the effect of reducing overall annual revenues as well as reducing carryover revenue from FY 1993 and 1994.



The Board of Pharmacy had revenues of \$805,961 in 1993 and \$839,793 in 1994. The Board's budget was \$511,849 for 1994 and 1995 is \$722,698.

During 1994, as required by law, the Board reviewed all of its regulations. The results of that review were that several regulations were either amended, repealed or enacted. These include:

- 10.34.02 Examination, Licensure and Internship (amended)
- 10.34.03 Acute Care Regulations (new)
- 10.34.07 Pharmacy Equipment (amended)
- 10.34.09 Fees (amended)
- 10.34.13 Reinstatement of Expired License for Pharmacists (amended)
- 10.34.16 Application Fee (repealed)
- 10.34.22 Licensing Wholesale Prescription Drug Distributors (amended)

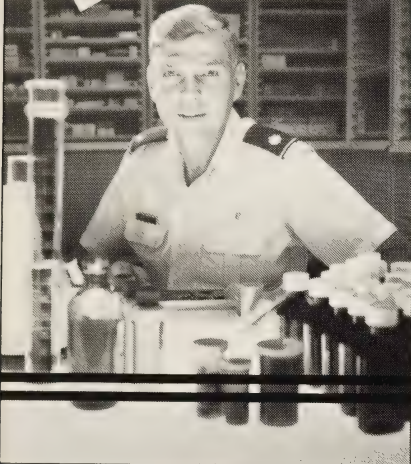
The Board has the following amended, new or repealed regulations in progress:

- 10.34.18 Continuing Education for Pharmacists (amended)
- 10.34.23 Long Term Care Facilities (new)

Continuing Education

Throughout the year, the Continuing Education Task Force has accepted requests for approval of Continuing Education programs when the providers are not included in the Maryland regulation. The new form included with pharmacist renewal applications has now been used for two renewal periods, 1993 and 1994. This form has allowed pharmacists to verify their documentation prior to the end

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of their renewal period. There is time for any pharmacists without a total of 30 continuing education units to obtain the amount needed or request an extension from the Board. This form also gives the Board and the pharmacist a reference list, if necessary, in the event that the pharmacist is audited. Since 14% of the pharmacists audited during 1993 were out of compliance, the number of pharmacists audited in 1994 was increased. The 1994 audit is currently in progress.

Secretary/Treasurer's Message

I have been on the Board of Pharmacy for four years now and it seems as if we have gone from one transition period to another. When I was first appointed to the Board, the staff consisted of an executive director and two others -- and one of them left. We were authorized more but hiring freezes made it impossible to fill vacancies. Shortly after that we were authorized a compliance officer. Three people have occupied that position in the last three years.

When the legislature allows us to have special funding, we filled in the staff with a computer specialist/fiscal officers, a new lead secretary and two additional positions which were needed to handle the work that other departments in the State had done for us. Since then, we have had a change in the office of Executive Director, the lead secretary has changed, and one other person has gone on an extended leave of absence. Even the counsel assigned by the Office of the Attorney General is new to the Board.

All of this has caused a year of great transition for us in fiscal 1995, but left us with great expectations for the future because of the quality of persons who have accepted the top positions. With Norene Pease as the new Executive Director, pharmacy-attorney Tracy Baroni filling the position of Pharmacist Compliance officer and Tamarra Banks as the computer specialist/fiscal analyst, the leadership is by far the strongest it has been in years perhaps ever. Backlogs of disciplinary cases are being dealt with aggressively by Tracy, systems are being refined by Norene to allow better efficiency, and responses to consumers and licensees are faster and more complete.

Much of our time this year has been spent defining the way the Boards and Commission are to operate within the fabric of our semi-autonomy. This should be complete in the next several months and allow us more time for our primary purposes.

The Board expects to be relocated later this year on the same floor we now occupy, probably with more space and a better layout. The first phases of computerization is about complete and we will shortly enter further into the electronic age with E-mail, completion of the new telephone system, and the expected purchase of scanning equipment to speed processing of renewals. A microfilm system to expedite research of records is next on the modernization agenda.

The long awaited regulations for pharmacies servicing acute care facilities and long term care facilities are about ready to surface. These will be guidelines for the way the Board expects the profession to practice in these areas. Likely, most pharmacies will have very little adjusting to do in the way they operate.

Our new toll free 800 number demonstrates our desire to be accessible to consumers and pharmacists in all areas of Maryland. **MP**

This report was presented to the MPhA House of Delegates at the 113th Annual Convention on June 19, 1995.

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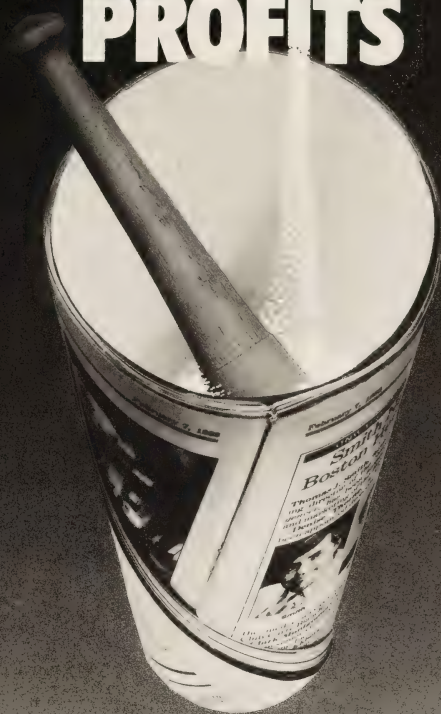
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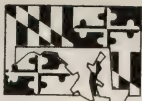
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Litigation Update

Patient Adds Refills

The Supreme Court of Alabama has recently exonerated a deputy sheriff of allegations that he falsely imprisoned and maliciously prosecuted a patient who attempted to obtain an unauthorized refill of a medication.

According to the Court's description of the facts of the case, the plaintiff had suffered an on-the-job injury when she struck her head on a metal bar. The plaintiff was treated at a local emergency room by a physician who prescribed Vicodin for her. The patient took the prescription to a pharmacy where it was filled. But the pharmacist later became suspicious that the refill authorizations marked on the prescription were not valid. The pharmacist

called the prescriber who informed the pharmacist that he had not authorized any refills on the prescription. The pharmacist called a sheriff's deputy, who told the pharmacist to note on the store's computer that he was to be called if the patient attempted to refill the prescription.



David Brushwood

Several days later the patient went to another pharmacy and requested that the prescription be refilled. The pharmacist at this pharmacy called the pharmacist at the first pharmacy and learned of the problem. The pharmacist at the second pharmacy called the deputy, who arrested the patient. Charges were filed against the patient, but they were dropped for reasons not given in the court opinion.

The patient then filed a civil lawsuit against the two pharmacies, and against the deputy. While the merits of the lawsuit against the pharmacies are not discussed in the opinion, numerous other cases of this kind have uniformly been decided in favor of

pharmacies and pharmacists who simply informed the proper official of a violation of the law. The case against the deputy was resolved favorably for the deputy because a police officer cannot be sued if he or she is functioning in good faith within the scope of his or her authority.

This case reinforces the need to screen refill authorizations under circumstances where it seems unusual for refills to be authorized. It also reinforces that pharmacists who are asked to refill a prescription from another pharmacy should always check with that other pharmacy. MP

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Bridging Education and Practice

The New Experiential Learning Program

*Magaly Rodríguez de Bittner, Pharm.D., BCPS
Assistant Professor, UMAB School of Pharmacy*

*Stuart Haines, Pharm.D., CDE
Assistant Professor, UMAB School of Pharmacy*

Over the past several years, the University of Maryland at Baltimore School of Pharmacy has developed and implemented a new curriculum for a four-year entry-level Doctor of Pharmacy (Pharm.D.) degree. The curricular changes were developed by the faculty with extensive consultation with local practitioners and national pharmacy leaders. Specifically, it was the school's intention to design a curriculum that would meet the present and future needs of our profession.

The central goal of the new curriculum is to provide students with the knowledge, attitudes, values and skills necessary to provide pharmaceutical care. In order to provide these services effectively, the student must learn to collaborate with patients and their families, prescribers, and other health care providers. Further, each student must learn how to provide pharmaceutical care in a variety of practice settings.

Ultimately, the goal to train the student to be a proactive health care provider who is able positively alter patient outcomes by improving their quality of life.

The curriculum is divided into two major components, one didactic and the other experiential, taught over eight semesters. One of the key elements of the new curriculum is the emphasis on developing competencies by integrating and inter-relating didactic and experiential learning. A fundamental part of the curriculum is that each successive course builds on previously acquired knowledge and skills. Each course requires the students to use previously learned material; in this way new concepts are linked to those previously taught.

Furthermore, innovative teaching methodologies are stressed and are evident throughout the curriculum. Much of the didactic coursework is accomplished through small group workshops, case discussions, self-learning assignments, and computer assisted activities. Assignments emphasize problem-solving and critical thinking skills. New course offerings introduce students to the cutting edge advances in biotechnology and drug development.

Flexibility is also a major goal of the curriculum. Students now have a wider range of elective choices. Students may elect to take a course of study, known as a "pathway," in a concentrated area. Pathways have been developed in research, management, pharmacotherapy and advanced practice.

The Experiential Learning component of the curriculum is a series of structured learning and training activities. Through experiential learning, students interact directly with experienced pharmacy practitioners in a variety of practice settings and environments. Experiential activities are directly supervised by preceptor faculty members. One innovative aspect of the new experiential learning program is that it has been designed to link the didactic courses. For this reason, students begin their experiential learning in the first semester of the Program.

The experiential learning program is composed of six phases, each with specific objectives. An overview of the process appears in Figure 1. The ELP has five goals:

- Provide pharmacy practice experiences throughout the four years of the curriculum.
- Link classroom learning with pharmacy practice experience.
- Provide experiences that enable students to develop the skills necessary to provide pharmaceutical care in multiple practice settings.
- Provide experiences that enable students to effectively provide services that have a positive impact on individual patients, populations of patients, prescribers, and health care systems.
- Allow flexible elective experiences for 25% of the experiential program enabling students to begin the process of differentiating knowledge and skills.

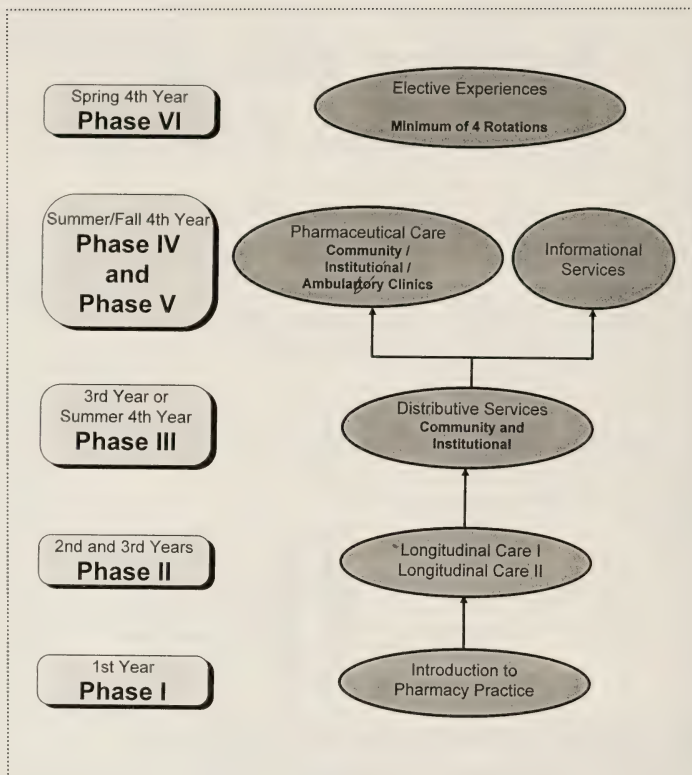


Figure 1

It is through experiential learning that students learn to efficiently perform distributive activities and to effectively deliver pharmaceutical care to patients. A total of 32 credits in experiential learning courses (a minimum of 1500 clock hours) is required. The successful completion of the experiential component is required to satisfy the requirements for licensure in Maryland.

The school is committed to involving pharmacy practitioners throughout the curriculum. Experienced practitioners are needed for case discussion sessions, pharmaceutical care rounds, lectures and panel discussions. Most importantly, practitioners serve as preceptors in the experiential learning courses.

Subsequent articles will discuss in detail the different phases of the experiential program, including the activities required in each.

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This lesson reviews three new drugs recently introduced to the US pharmaceutical market.

Aprotinin

Trade Name: Trasylol

Aprotinin (Trasylol: TRAY-sil-ol) is a naturally-occurring polypeptide with a complex, and not fully understood mechanism of action. Classified as a protease inhibitor, it is indicated for use in the reduction or prevention of blood loss in high-risk patients undergoing coronary artery bypass graft (CABG) surgery. It is also approved for use in selected cases of primary CABG surgery where the risk of bleeding is particularly high (impaired hemostasis: e.g., recent or current use of aspirin or other anticoagulants). The decision on whether to use it in primary CABG surgery patients is based on the risk of renal dysfunction and on the potential for anaphylaxis, should a second surgical procedure be required where the drug would be necessary.

Aprotinin was approved in 15 countries for a variety of blood loss related conditions prior to its approval in the U.S. It was first used in the U.K. 30 years ago for pancreatitis.

Aprotinin has orphan drug status. An orphan disease is defined as one that affects fewer than 200,000 persons in the U.S., or more than 200,000 persons in the U.S. for which there is no reasonable expectation that the

New Drugs Review: Aprotinin, Calcipotriene, and Stavudine

*Thomas A. Gossel, R.Ph., Ph.D., Dean
Ohio Northern University*

*J. Richard Wuest, R.Ph., Pharm.D.
Professor of Pharmacy Practice, University of Cincinnati*

A professional development program made possible by
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cost of developing and marketing the therapeutic agent would be recovered under the current FDA approval system.

Aprotinin is an antifibrinolytic agent and a protease inhibitor. Its precise mechanism of action is complex and largely unknown. The drug inhibits a number of enzymes including plasmin, trypsin, chymotrypsin, plasmin-streptokinase, and kallikrein. The strength of its activity against this latter enzyme. The primary effect of the drug during CABG surgery is attributed to maintenance of platelet function is the most common and clinically relevant hemostatic change.

Aprotinin is generally well tolerated. Adverse effects reported with its use are associated with complications of open heart surgery (e.g., atrial fibrillation, myocardial infarction,

and heart failure) and are not necessarily attributable to aprotinin therapy. For example, in studies representing 364 patients treated with aprotinin and 235 patients who received placebo, one or more adverse events was reported in 70 percent of both groups, atrial fibrillation (25 percent in aprotinin-treated vs. 22 percent with placebo), myocardial infarction (10 percent vs. 7 percent), and heart failure (8 percent vs. 6 percent).

There is concern about anaphylactic reactions which occur more frequently with repeated drug administration. According to its labeling, 13 cases of anaphylaxis including four deaths were reported in 7,000 patients who had prior exposure to the drug. In 140,000 patients who were first-time recipients, five incidents of anaphylaxis with one death were noted. Its manufacturer states that

anaphylaxis has been reported in less than 0.5 percent of patients in postmarketing trials outside the U.S.

Aprotinin is useful for reducing blood loss and the need for blood transfusions during cardiopulmonary bypass surgical procedures. There may be additional benefit during liver transplantation and peripheral vascular surgery. Aprotinin appears to be useful pharmacologic agent for this.

Because of its high cost and potential for serious toxicity, some authorities argue that it should not be used routinely in cardiac surgery. Its use in first-time surgeries is also questioned since many of these patients will not lose excessive blood, and the drug places the patient at an increased risk for allergic reactions if it is needed in later (or subsequent) cardiopulmonary bypass procedures.

Since aprotinin prolongs the whole-blood clotting time, the standard method for monitoring heparin levels may not be accurate. Its use in patients with cardiopulmonary bypass grafts (e.g., maintaining the activated clotting time above 400 and 450 seconds) may lead to inadequate heparin dosing.

Therefore, it is recommended that the standard loading doses of heparin be administered prior to surgery. Additional heparin can be given as needed, either by a fixed dose regimen based on patient weight and duration of the procedure, or on the basis of heparin levels measured by a method that is not affected by aprotinin, such as protamine titration.

Aprotinin, Calcipotriene, and Stavudine

| Generic | Trade Name | Availability | Dosing |
|---------------|------------|--------------------------------------|--|
| aprotinin | Trasylol | 1.4mg/ml in vials of 100 and 200 ml | Test dose of 1 ml IV 30 min. pre-op; then loading doses of 200mL over 20-30 min.; then 50 mL/hr. |
| calcipotriene | Dovonex | 0.005% ointment | Apply thin layer to affected skin BID |
| stavudine | Zerit | 15, 20, 30, & mg capsules Q 12 hours | 40 mg BID, 40 |

Table 1

The recommended dosage regimen includes a test dose of 1mL (1.4 mg) intravenously 30 minutes before surgery. If no allergic reaction occurs, 200mL is infused over 20 to 30 minutes after induction of anesthesia. During the surgical procedure, the drug is infused at a rate of 50mL/hour.

Trasylol is available in vials containing 10,000 KIU/mL (KIU = Kallikrein Inhibitor Unit). This equals 1.4mg/mL aprotinin.

Calcipotriene

Trade Name: Dovonex

Calcipotriene (Dovonex - DOE-va-nex) is a synthetic vitamin D derivative that inhibits cell proliferation and stimulates cell differentiation. It is indicated for the treatment of moderate psoriasis.

Psoriasis

From one to three percent of Americans are reported to be afflicted with psoriasis. It is an extremely serious disorder to its sufferers because plaques visible on exposed areas of the body may cause them to avoid social contact with the public.

Psoriasis, a chronic inflammatory skin condition, is characterized by pink or dull-red lesions that have distinctive borders and are covered with thick silvery colored scales. If these scales are removed, the underlying skin may bleed, a phenomenon referred to as **Auspitz's sign**. Some patients experience constant scaling associated with itching and discomfort, while others may undergo variable periods of remission. The most characteristic symptom is chronic itching, noted in over 80 percent of patients.



Patient Compliance:

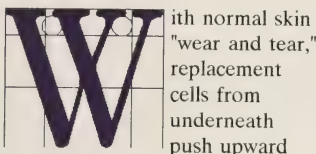
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Lilly

The designation psoriasis vulgaris describes the disease that results when lesions coalesce into large, usually symmetrical areas. These are most commonly seen on the elbows, knees, and lower back.

Psoriasis is characterized by alterations in the epidermis. This leads to rapid cell turnover, along with inflammation of the underlying capillaries. Epidermal cells are continually formed from the lower skin layers. Young cells migrate upward toward the skin's surface. In healthy skin, there is insufficient nutrition to sustain their life and they die as they approach the surface and dehydrate. These dead, dried, and high compacted cells comprise the keratin (stratum corneum) layer.



and the outermost layer of keratin sloughs off continually. This ordinarily requires three to four weeks for completion. In psoriasis, however, the keratin turnover rate is increased to three to four days. Consequently, both live and dead cells accumulate on the skin's surface to form the thickened, scaly patches that have the characteristic silvery appearance.

The immune system may also play an important contributory role in psoriasis. For example, IgG levels can be detected in psoriatic lesions. IgG is the most important of the immunoglobulins (antibodies) that are responsible for combatting infection and invasion by foreign protein. One hypothesis suggests that patients

with psoriasis lose the suppressant action of their immune system, and antibodies form in response to skin antigens. This permits formation of antigen-antibodies complexes, a leukocyte response, and eventually the inflammatory lesion characteristic of psoriasis.

Although many other theories have been advanced to explain the causes of psoriasis, no single hypothesis explains all ramifications. Several therapies alleviate the condition, including the vitamin D derivative calcipotriene.

Vitamin D is best known for its role in the regulation of intestinal calcium absorption, bone mineralization, and prevention of rickets. Vitamin D₃ (cholecalciferol) is formed in human tissues via ultraviolet (UV) irradiation of 7-dehydrocholesterol. Vitamin D₃, in turn, is hydroxylated in the liver and kidney to 1,25-dihydroxyvitamin D₃, the biologically active metabolite.

The physiologic effects of 1,25-dihydroxyvitamin D₃ are achieved when it binds to vitamin D receptors (VDRs). These receptors are found in numerous cells not involved with regulation of calcium metabolism. These include human epidermal keratinocytes, dermal fibroblasts, hematopoietic cells, and many cancer cells. In human epidermal keratinocytes and other cell types, 1,25-dihydroxyvitamin D₃ has been shown to inhibit cell proliferation and induce cell differentiation. This, along with knowledge that systemic effects on calcium and bone metabolism are at least 100 to 200 times less than those of 1,25-dihydroxyvitamin D₃, was the basis for development of

Patient Information for Calcipotriene

1. Apply the ointment twice daily.
2. Avoid application to the face.
3. Wash hands after application
4. The maximum dosage is 100 gm/week.
5. The ointment can be combined with UVB radiation for enhanced efficacy.
6. There is no clinical experience with use of the ointment during pregnancy or in children.

Table 2

calcipotriene and other synthetic vitamin D derivatives to be used in the treatment of psoriasis.

The VDR binding sites are of the same type as those for other steroids such as estrogen, glucocorticoids, and retinoic acid. A single VDR type is believed to be common to all cells and tissues. Calcipotriene binds to VDRs in many cell types with the same affinity as 1,25-dihydroxyvitamin D₃, and mediates the receptors' actions.

The drug exerts immunologic effects that are qualitatively and quantitatively similar to actions of 1,25-dihydroxyvitamin D₃. These include inhibition of thymocyte (cells of thymus origin; precursors of T cells) proliferation induced by interleukin and reduction of immunoglobulin production by interfering with T-helper cell functions. Calcipotriene has also

been shown to inhibit lymphocyte proliferation in mononuclear cells and some epidermal cells. These actions on immune function may contribute to the drug's overall benefit in the treatment of psoriasis.

The most common adverse effects noted in clinical trials were burning, itching, and skin irritation, occurring in approximately 10 to 15 percent of patients. Side effects reported in 1 to 10 percent of patients included erythema (redness), dry skin, peeling, rash, and dermatitis. Worsening of psoriasis, including development of facial and scalp psoriatic lesions and dermatitis, was experienced at the same

level. The dermatitis appears similar to that caused by topical corticosteroid therapy.

The label warns that the ointment should not be applied to the face. It can cause irritation of lesions and surrounding uninvolved areas, as well as reversible elevation of serum calcium. Patients should wash their hand thoroughly after applying it. The ointment is contraindicated in patients with demonstrated hypercalcemia or evidence of vitamin D toxicity.

Safety and effectiveness of calcipotriene in children have not been established. Geriatric patients may also be at greater risk for side effects. The result of an analysis of severity of skin-related adverse events showed a statistically significant difference for patients over 65 years (more severe) compared to those under 65.

Clinical trials have demonstrated improvement of moderate plaque psoriasis that usually begins after two weeks of therapy. The product's labeling stresses that this improvement continues with approximately 70 percent of patients showing at least marked improvement after eight weeks of therapy. Ten percent show complete clearing. If treatment is stopped after 4 to 8 weeks, the disease gradually recurs at a rate consistent with its natural progression. Recurrence takes place in 1 to 2 months, on average. Exacerbation has not been observed on discontinuing therapy. Lifetime treatment may be required for sustained control of the disease.

Calcipotriene can be used concomitantly with UV-light therapy, and the combined therapy is superior to calcipotriene alone. This is noted in the number of patients who obtain complete clearance with combination therapy.

It is difficult to ascertain the place of topical calcipotriene in the therapy of psoriasis. Some reports place it as a first-line drug, others do not.

Patient Information for Zerit

Zerit is used to treat HIV infections and other conditions as determined by your doctor.

- Take Zerit with a full glass of water. If stomach upset occurs, you may take Zerit with food unless directed otherwise.
- It is important that you take this medicine as instructed. Do not skip a dose or stop taking the medicine without asking your doctor.
- Since Zerit helps control your condition, you should continue to take it, as long as your doctor tells you, even if you are feeling well.
- Zerit will not cure your infection and you may continue to acquire illnesses associated with HIV infections. Contact your doctor if there is any significant change in your health.
- If you miss a dose of Zerit, take it as soon as possible. But, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose, unless your doctor has instructed you otherwise.
- Keep Zerit at room temperature, in its original, labeled container and out of the reach of children. In case of accidental ingestion or overdoses, call your doctor or poison control center immediately. Do not keep or use outdated medication.

Every medicine is capable of producing side effects. Most patients experience few or no problems while taking Zerit. However, be sure to tell your doctor if the following occur: burning sensation and numbness of fingers and/or toes, persistent headache, chills, fever, stomach or back pain, nausea, vomiting or diarrhea, or any other unusual, bothersome effects.

Adapted from the Pharmex PALS (Patient Advisory Leaflets).

Table 3

Calcipotriene should be applied to the affected skin, in a thin layer, twice daily and rubbed in gently and

completely. Calcipotriene is available as Dovonex ointment, 0.005%. It is marketed in tubes containing 30, 60, and 100g. Information useful in counseling patients is presented in Table 2.

Stavudine

Trade Name: Zerit

Stavudine (Zerit - ZER-et), also known as d4T, is an antiretroviral nucleoside analog that inhibits Human Immunodeficiency Virus (HIV) replication. It is the fourth drug in its class, joining zidovudine (Retrovir/AZT), didanosine (Videx/ddI), and zalcitabine (Hivid/ddC).

Stavudine is used in the treatment of adults with advanced HIV infections who are intolerant of approved therapies (e.g., Retrovir), those who have experienced significant clinical or immunologic deterioration while receiving these therapies, or those for whom such therapies are contraindicated.

Stavudine enters HIV-infected cells where it is phosphorylated by viral enzymes into its monophosphate form. This, in turn, is further metabolized by intracellular enzymes to the diphosphate and triphosphate forms. The triphosphate salt is the active form that selectively inhibits HIV-reverse transcriptase. This enzyme is required by HIV to replicate. This mechanism is identical to that of zidovudine and the others.

Studies of patients taking stavudine and zidovudine concomitantly have demonstrate that zidovudine inhibits the phosphorylation of stavudine. Stavudine, on the other hand, does not inhibit the phosphorylation of zidovudine. Combining these two drugs, therefore, is not considered to be advantageous over zidovudine therapy alone.

The toxicity of greatest concern is peripheral neuropathy which has occurred in 15 to 21 percent of patients in clinical trials. It is characterized by a burning sensation and numbness of the fingers and/or the toes. These can become progressively worse and more painful, and may be irreversible if the drug is not discontinued in a timely manner.

Drugs that can also cause peripheral neuropathy should be avoided if possible in patients receiving stavudine. These include chloramphenicol, gold salts, hydralazine, isoniazid, metronidazole, nitrofurantoin, phenytoin, and vincristine.

Bone marrow toxicity has not been a significant adverse effect in studies to date, an advantage over zidovudine. Anemia has been observed in some patients, but significant leukopenia or thrombocytopenia.

Stavudine has shown efficacy in the treatment of adult patients with acquired immunodeficiency syndrome (AIDS), and AIDS-related complex (ARC). Significant increase in CD4 cell counts, weight gain, and an

Continuing Education

Goals

The goals of this lesson are to identify and discuss the actions and reactions of three new drugs introduced into therapy during 1994-95.

Objectives

At the conclusion of this lesson, successful participants should be able to:

1. exhibit knowledge of the pharmacologic classification and therapeutic considerations for the drugs discussed;
2. select from a list, the indications, mechanisms of action, benefits and limitations of the drugs presented;
3. identify adverse effects, major toxicities, and drug interactions associated with these products; and,
4. demonstrate an ability to counsel patients on the drugs reviewed.



This program has been approved for one credit hour (0.1 CEUs) of ACPE approved continuing education. The Maryland Continuing Education Coordinating Council is an approved provider for continuing education programs for pharmacists by the American Council on Pharmaceutical Education.

ACPE # 186-144-95-020.

improvement in constitutional symptoms have occurred by the sixth week of therapy in patients with AIDS or ARC.

The drug should be useful for patients developing resistance or intolerance to other antiretroviral agents.

There are no data that evaluate the effect of stavudine on the progression of HIV infections. Its ultimate place in therapy is unknown at this time, but it is encouraging to find new agents effective against the AIDS virus.

Oral therapy with stavudine is associated with significant increases in, or stabilization of, CD4 cell counts in many patients. Improvement in clinical symptoms (e.g., diarrhea, fever, fatigue) and weight gain have also been observed during therapy. In many patients, however, CD4 cell counts have returned to pretreatment levels or below following prolonged therapy (12 weeks or longer) with stavudine.

Stavudine is available in 15, 20, 30, and 40mg capsules. The usual dose is 40mg approximately 12 hours apart for patients weighing more than 60 kg. Lower doses are indicated for smaller patients.

Information useful in counseling patients is presented in Table 3. **MP**

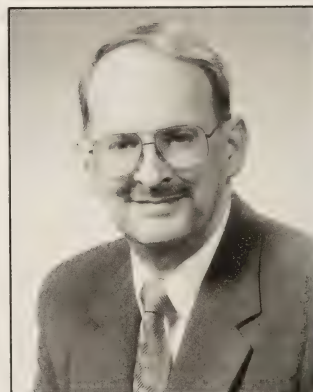
Interactions...

Managing Diversity in Education and Practice

As this year's graduating class stood on May 19th, and publicly recited the Oath of a Pharmacist, the words "... service of all humankind..." echoed throughout Westminster Hall. As I looked out on the audience of faculty, students, families, and friends, I realized the presence of diversity and its importance both personally and professionally to our graduates and the patients they will serve.

Even before President Clinton's recent order for a review of federal laws involving affirmative action, questions about the appropriateness of affirmative action in the work place and on college campuses had surfaced. Critics try to make affirmative action the scapegoat for many of the ills of society. However, without a doubt, the world is becoming an increasingly diverse society. Statistics show that what we refer to as minorities are rapidly becoming the majority. Within the next 50 years, over half of the population of the country will be made up of African-Americans, Hispanics, and Asian Americans. In the academic arena, we can expect our student population to diversify even more rapidly. The potential impact on education was a topic at a recent conference of the Association of Academic Health Centers/Federation of Association of Schools of the Health Professions.

One speaker, University of North Carolina Professor of Geography, James Johnson, pointed out that the group of issues involving managing diversity on campus includes things other than race. Gender issues are also prominent. The burden for pharmacy, where female students have been in the substantial majority for years and where the number of female faculty has grown rapidly, is evident. With a larger and more routine involvement of women in pharmacy, a variety of family issues must be managed both among students and faculty. In addition, there will need to be increased awareness of what constitutes sexual harassment.



David A. Knapp, Dean
UMAB School of Pharmacy

Race and ethnicity are a central concern. Because of changing demographics, schools in general are challenged to bring the ethnic proportion of students and faculty members in line with geographic populations. In addition to serving legal and moral requirements, the increased proportions allow faculty members to serve as role models and mentors to students and permits students to be exposed to different background and viewpoints. But compared with the general population through out the country, African-Americans are under represented in pharmacy faculty by a factor of three; Hispanics are under represented by a factor of four; and Asian Americans are over represented by a factor of two. These are not necessarily the most appropriate comparisons--and I am not suggesting that our faculty should be distributed in an equivalent way to the general population--but the numbers are suggestive.

The Americans with Disabilities Act, the federal civil right law enacted to protect persons with disabilities from discrimination in employment, government services and programs, transportation, public accommodations, and telecommunications, gives new visibility to a host of educational and employment issues ranging from the need for facilities modification, to the provision of special services at public seminars and lectures, to serious consideration of what disabilities, if any, might prevent a student from successfully completing the doctor of pharmacy degree.

Finally, managing diversity means paying attention to even white males! North Carolina's Dr. Johns stressed that accomplishing an optimal and diverse workplace means affording an environment within which students, faculty members, and staff are comfortable enough to perform to the limits of their abilities. This admonition can also be extended to the classroom: an environment must be created that allows students to contribute optimally. How? By minimizing distractions and distresses due to individual differences so that greater productivity is achieved.

In recognition of these needs, the University of Maryland at Baltimore is commit-

ted to a diverse student, faculty, and staff population. The School of Pharmacy is committed to creating an interdisciplinary educational environment that goes beyond the tradition classroom so as to expose students to a variety of learning experiences. We strive to bring together a diverse group of people who can learn from one another and bring that knowledge into their professional lives. Once a student graduates and is working within the community, he or she will be expected to assess the individual and remove barriers that impede the delivery of pharmaceutical care. The pharmaceutical care concept means that for their professional lives, these students will be involved in caring, spending time, counseling, recommending, and following up with patients of *all income levels and backgrounds* in order to assure that patient achieve optimal outcomes from drug therapy. So the students who have not had the opportunity to come into contact with persons of other races, religions, education, ages, sexual preference or social class will be at a distinct disadvantage. Our classes and experiential learning must prepare students to care across the wide range of human experience. **MP**

Adapted from an editorial in *American Journal of Pharmaceutical Education*, Vol 59., Spring 1995.



Continuing Education Quiz

July 1995 -- Aprotinin, Calcipotriene, Stavudine

This month's questions are taken from the article on aprotinin, calcipotriene, and stavudine that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members \$5.00). The completed quiz for this issue must be received by December 31, 1995. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name _____

Address _____

City/State/ZIP Code _____

1. Aprotinin inhibits which of the following enzymes?
 - a. Cyclo-oxygenase
 - b. Monoamine oxidase
 - c. Protease
 - d. Reverse transcriptase
2. Aprotinin is indicated for use in:
 - a. coronary artery bypass graft surgery
 - b. myocardial infarction secondary to atherosclerosis
 - c. prosthetic replacement of the mitral valve
 - d. transurethral resection
3. The strength of Trasylol is expressed in terms of KIU which refers to:
 - a. kallikrein
 - b. calories
 - c. kilograms
 - d. kalirium
4. Calcipotriene is a derivative of:
 - a. calcium
 - b. parathyroid
 - c. vitamin A
 - d. vitamin D
5. The therapeutic effect of calcipotriene is due to:
 - a. increasing cell proliferation
 - b. inhibiting cell proliferation
6. Dovonex ointment is contraindicated in patients with demonstrated:
 - a. hyperkalemia.
 - b. hypercalcemia.
 - c. hyperglycemia.
 - d. hyperchloremia.
7. Patients using Dovonex ointment should be advised to all of the following *except*:
 - a. apply a thin layer twice a day.
 - b. rub the ointment in gently and completely.
 - c. adequately cover the affected areas on your face.
 - d. wash your hands after use.
8. Patients taking Zerit should be given all of the following advice *except*:
 - a. take the capsules with a full glass of water.
 - b. in order to cure your infection, you must take the medication exactly as directed.
 - c. if you miss a dose, take it as soon as possible.
 - d. tell your doctor if you notice a burning sensation and numbness in your fingers and/or toes.
9. Stavudine inhibits which of the following enzymes?
 - a. Cyclo-oxygenase
 - b. Monoamine oxidase
 - c. Protease
 - d. Reverse transcriptase
10. The usual dose of Zerit is:
 - a. 15 mg once daily.
 - b. 20 mg QID
 - c. 30 mg TID
 - d. 40 mg BID

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August 1995

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800-369-7424

Jeff Fantle
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301-816-0328
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Stanley Bortnick
Area Manager
410-315-7970
800-369-7424

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410-653-1549
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MARYLAND PHARMACIST

The Official Publication of the Maryland Pharmacists Association

August 1995

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President's Commentary

Of Baby Boomers and Dinosaurs

As one of the first of the Baby Boomer generation, I also represent one of the last dinosaurs of community pharmacy. At least that's what some of our younger Association members have told me. It's true, I operate a traditional neighborhood pharmacy. It's hard to think of yourself as a dinosaur at age 46, but I'm afraid that's true, too.

But being a dinosaur does have its advantages. It means you've been around long enough to pontificate about the past. It means you got to see the birth and evolution of new things. For example, the day predicted 30 years ago by pharmacy academia that we needed a 5 year degree has finally arrived.

And, being a particularly observant dinosaur, I can stand here and reflect on all the changes and controversies of the past few years. For example, I can discuss managed care versus traditional care versus Hillary-Care. I can review the plight of the pharmaceutical companies who are so poor that they're forced to spend their double-digit profits on third-party processors and mail-order pharmacies. But talking about the past doesn't change anything.

We must remember that one of the purposes of the MPhA is not to cure all the perceived ills of this profession. But rather, our mission is to disseminate the information our members need to make practical, informed judgements about pharmacy practice both today and tomorrow. If along the way we can prevent a few poorly conceived programs from being implemented, we are so much for the better.

This brings us back to the original questions "Why do we have a dinosaur as President?" and "What does he intend to do for the Association?"

Let me answer the second question first. As President of MPhA, I will do nothing at all -- by myself. The President is a member of a team, our Board of Trustees. Together we seek to give direction to and keep focus for the Association. Therefore, I will recommend for the Board's consideration the following.

First, we must examine the problems of employee pharmacists and single pharmacy

proprietors who today are being called upon to dispense large numbers of prescriptions, provide some manner of patient counseling, and find themselves spending more time with an insurance company than the patient. We cannot permit the sweatshop mentality that have pharmacist working six, eight, twelve hours without a break. We cannot permit our members and the pharmacists of Maryland to be placed in a position where filling too many prescriptions result in too many errors. The problem is becoming so acute that some Boards of Pharmacy have levied large fines (\$25,000 and more) for under staffing and are looking a hourly quotas. At our 113th Annual Convention, our House of Delegates adopted a policy directing our Board of Trustees to do just that.

A second area I hope to expand into is a long-term commitment to educate the public on what is good about pharmacy care. Within the past several weeks while practicing pharmacy among the garden hoses and potting soil, I conducted a very informal survey with some of my patients. I asked them whether or not my pharmacist was providing them with good pharmaceutical care.

Some patients were very sure that they got the best in pharmaceutical care. Others had no idea what I was talking about but they believed that they were receiving good care. One patient was



James Tristani, P.D.
1995-96 MPhA President

particularly impressed with the amount of drug information leaflets we stuff into her prescription bags. A second one was even more impressed with our computerized kiosk that dispenses pharmaceutical advice and coupons at the same time. She thinks that's great because then she doesn't have to bother the druggist. Another patient said our care was great -- he got the right medicine, the right directions, and all in less than 5 minutes.

Last but not least, my personal favorite was the nice elderly lady who said our care was so good she would never go elsewhere. Feeling especially proud of our service, I asked her why she felt that way. And she told me that the lady who rings up our cash register has the same problems as her mother and she likes to compare notes.

Not one patient mentioned any interaction or lack of interaction with the pharmacist.

If these patients are typical, a large segment of the population has no idea what constitutes good pharmacy care. Is it any wonder that payers view pharmacy as nothing more than drug dispensers... that pharmacy is something that can be done by a mailman, a robot or an orangutan. We can educate 10,000 exceptional, clinically oriented pharmacists, but as long as the public perceives no value from us, we have no right to expect reimbursement from them.

But, once patients are educated to recognize what good pharmaceutical care is, it will take on a value separate from the drug. Patients would expect to pay for knowledge just as they do with their physicians. And once the public perceives this kind of treatment as a standard, the insurance companies would be forced to pay for it.

I would like to conclude with the answer to the first one of my two questions. Why do we have this dinosaur as President? Because this dinosaur is like some of its real animal ancestors. It will adapt to the catastrophic changes within the pharmacy environment, evolve and emerge as a graceful bird leading the flock into the 21st Century. **MP**

President Thuman's Comments on the growth and development of the profession were delivered at the 43rd Annual Convention, Board Meeting on Tuesday, June 20, 1995 at the Sheraton Ocean City Resort Hotel, Ocean City, Maryland.

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Interactions

Caring, Discovering, Educating and Leading

This summer marks the midpoint for students enrolled in the first class of the four-year professional Doctor of Pharmacy curriculum. It is the School's half-way point in the transition to an all Pharm.D. curriculum, so it is time to report on our progress and some of the challenges we still face. During this transition, our motto has been: Caring, Discovering, Educating, and Leading.

Caring

The training and knowledge we impart to our students is only effective if translated into helping people. Our students and faculty have enriched their own lives and the lives of others by participating in educational outreach programs. Some of these include: 1) the Maryland Poison Center whose staff respond to emergency, treatment, and information requests from the public and medical community concerning poisonings; 2) the Office of Substance Abuse Studies whose staff disseminates substance abuse information; 3) the Mental Health Pharmacy Program, a joint venture with the Developmental Disabilities Administration and Mental Hygiene Administration whose staff work to provide all aspects of pharmacy practice within the state's mental health facilities.

Through clinical community services, we have formed new partnerships with hospitals, community pharmacies, and chains, to broaden our presence in the community. For instance, we have worked in the empowerment zone through the Enhancing Neighborhood Action by Local Empowerment (ENABLE) program and the Community Health Workers (CHW) program. Both ENABLE and CHW assist members of the local communities who face a myriad of problems that affect their health and, thus, their quality of life.

All these programs need funds in order to survive, however, so we must continue to work with officials to seek solutions to our chronic underfunding problem.

Discovering

Some faculty and students are involved significantly in scholarship and research that contribute to drug discover, development, and use. From basic science laboratories, to industrial manufacturing facilities, to the bedside, and to public policy venues, other faculty, by working on research that not only adds to the store of knowledge but also strengthens our teaching programs, are engaging in cutting edge scholarship. Thus, our faculty improve their capabilities and become even better able to succeed in the classroom, in teaching laboratory, and in clinical settings.



Dean David A. Knapp

Scholarship in the School is leading to patents, publications, presentations, and recognition. The FDA contract is acknowledged to have reduced the approval time for abbreviated New Drug Applications by over 50 percent. The pharmaceutical services project is improving drug use in the Maryland Medical Assistance Program. Faculty are collaborating across schools on campus and with industrial organizations. These partnerships strengthen everyone.

Educating

This past May marked the graduation of the last five-year baccalaureate class (47 students) as well as the last of the post-baccalaureate Pharm.D. (25 students). The Graduate School of UMB conferred 13 doctoral and one master's degree on our students. This was one of the largest groups in recent years. We are committed to strengthen the management skills of our graduates and have entered into an agreement with the University of Baltimore to help us in this area. We have also increased the number of electives within the curriculum in order to broaden the choices available to the students.

Concluded on page 29....

On The Subject of Letters

*Melvin Rubin, P.D., Secretary and Commissioner
Maryland State Board of Pharmacy*



I have said in a previous article that it would be good if pharmacists were to practice in such a way that the Board of Pharmacy does not receive letters -- meaning letters of complaint from consumers.

Then a letter of another color came in -- a well written letter with constructive points for the Board to consider. This particular correspondence came from an old friend and colleague from my most active days in the Maryland Pharmacists Association, S. Ben Friedman. It appears that many perceptions are that the Board is always telling pharmacists what they must do in order to protect the public. We should, and do, want to hear what you think should be done.

Ben's first point was that the physician should be required to write the diagnosis on each prescription. He points out that this would aid in interpreting a poorly written prescription with look-alike, sound-alike drugs indicated. The pharmacist could not only determine if the medication is appropriate but would be better able to accurately fill the prescription. My response is that the

idea is great and the Board will look into working with the physicians for this; however, we have to wrestle with the problem of whether you could fill a prescription which omitted a required diagnosis when you could not reach the doctor.

His second point relates to a problem with the use of generics. Although the medication in an equivalent generic is the same as the originator brand, identification could be a problem. It will certainly have a different name and appearance -- perhaps even a refill of a generic will be hard to identify compared to the first one dispensed. Dr Friedman suggests having both the brand and generic name on the Rx label. Good idea. Unfortunately it is not so simple since you cannot give the impression that you are dispensing the brand, and the manufacturers may have a say in using their trademark name to identify a competitor's product. It is an area that needs attention and we are open to suggestions. A patient who is left with doubts that the medication is correct is not a happy camper. The law requires that you inform the patient in writing when a change is made, but changing from one company's generic to another does not require notification by law. At a minimum, use some mechanism to inform the patient up front to minimize apprehension. It will take less of your time to do this than to explain a difference the patient found on their own.

Another point made is that the increase in clinic practice has multiplied the problem of identifying and locating the prescriber. More often than ever we now receive prescriptions written on "generic" Rx blanks, without the physician name, phone number and other information imprinted. Although the law requires that prescribers write their name clearly on prescription blanks, we all know this is often not done. The Board should, and will, work with other disciplines to try to minimize this problem. It is real, and could lead to errors including filling prescriptions written by non-authorized prescribers unless the pharmacist takes the time needed to verify the authenticity. It just adds to the problem we have experienced with stolen prescription blanks. Keep in mind that the Board of Pharmacy does not license physicians and that dealing with issues of this type require cooperation from the Board of Physician Quality Assurance.



Dr. Friedman then points out a possible problem that some Board members are greatly concerned about, which has a large grey area making it difficult to deal with. These days more than ever, there is a pinch on profits in pharmacy which naturally leads to our own cost-containment requirements. Since salaries are such a large part of over all pharmacy costs, it is natural to look there for potential savings. Pharmacists are asked to fill more prescriptions with less support help. Often, because there is not enough profit to allow overlapping pharmacist hours, the easiest way to arrange a schedule is for pharmacists to work a 12 or 13 hour day, perhaps alternating with a day off.

Is this bad in all cases? Perhaps most pharmacists are not as sharp in the 11th hour as the 2nd hour. But some like this type of schedule. A pharmacist in one of my stores prefers even 2 or 3 long days in a row, then long weekends off. The determinant should always be the public safety and in my opinion each circumstance must be weighed individually. Nurses often work 'double' shifts -16 hours. Physicians, especially as residents, work even longer on occasion. My personal feeling is that enough leeway should be offered for pharmacists to feel comfortable with their schedule while taking into consideration management problems and above all, public safety.

The area of support help is another thorny one. Pharmacists have been known to complain about too little support help and others about having too much support help to have to supervise. The Board will emphasize that pharmacists should not be required to practice in situations which could increase error potential and that hard and fast rules that apply to every circumstance in the same way may well cause problems with public safety.

All of the above points are legitimate issues, with varying degrees of complexities. Viewpoints from pharmacists are important to give us a clear idea of what you think would minimize the risk of error to the patient. Specific recommendations which take into account public safety, as well as employer and employee problems, are very welcome.

Perhaps more well thought out and well written letters like Ben Friedman's would not only give the Board a better sense of the problems and frustrations facing the licensees, but give a new perspective on potential solutions. And, of course, they give us documentation to help proceed with any changes we might consider necessary. You may be able to put a new light on a subject we have been looking at with tunnel vision. Employers, from independent owners to chain officials, are encouraged to offer their thoughts also.

I can't promise to answer all of your letters, let alone write a story on them. In the meantime, Ben -- thanks for your thoughts and please say hello to Bea for me.

MP

A New Frontier for Pharmacy

A Look at MPhA's 113th Annual Convention

From June 18 to 21, more than 200 pharmacists and their families took part in the Maryland Pharmacists Association 113th Annual Convention in Ocean City. Intermingled with continuing education programs on implementing pharmaceutical care, billing for cognitive services, and updates on treatments for hyperlipidemia and diabetes were lots of social events, food fests, and opportunities to just relax and have fun.

Aside from the learning and the playing, the MPhA Convention is also an opportunity for pharmacists statewide to join together, hear about the Association's accomplishments, and debate future directions for the organization. The MPhA House of Delegates, comprised of more than 80 pharmacists from every conceivable area of practice, met on Monday, June 19 and Tuesday, June 20 to hear reports from the Association's standing Committees and to discuss member-submitted resolutions.

The following pages highlight the written reports from MPhA's Committee Chairs and review the policy statements adopted.



Pharmaceutical Care Committee

Chair: Timothy Lubin, P.D.

The expansion of pharmacy practice into the realm of reimbursable cognitive services has begun. Under the direction of MPhA President Arnold Davidov, the Pharmaceutical Care Committee was created in

the fall of 1994. The objective of the Committee was to facilitate the implementation of cognitive services and serve as a support to the MPhA membership during these transitional times.

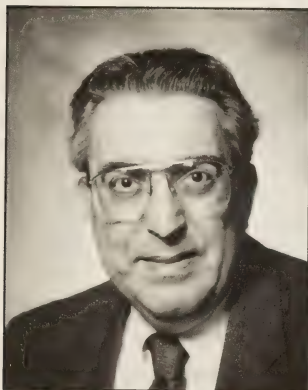
Education support is a priority, focusing on specific disease states, the development of pharmaceutical care plans, documentation and monitoring of therapeutic outcomes. Dave Miller was instrumental in creating the Pharmaceutical Care Foundations Program which started in November with a day long program on Asthma. The MPhA will continue to focus continuing education on the development of pharmaceutical care plans and outcomes based practice.

Other challenges confronting pharmacists during this evolution are the issues of reimbursement and the integration of cognitive services into existing dispensing practice. At the Convention Gene Memoli, a pharmacist from Connecticut, will share with us his experiences in billing and consultant services.

Numerous topics need to be addressed concerning their potential impact on the development of cognitive services. Currently the Committee is reviewing the scope of Pharmacy Practice Act for the possibility of incorporating changes which will foster the implementation of pharmaceutical care.

The certification of technicians may serve as a means of creating more time for patient counseling. The certification of pharmacists for specific disease states may raise the level of care and create a recognizable standard of value for reimbursement.

Dialogue and the collaboration of ideas are paramount during this evolution of our role in the health care system. The Committee needs pharmacists interested in charting the future of pharmacy practice.



Past Presidents Council

Chair: Nicholas Lykos, P.D.

According to MPhA's bylaws, the Past Presidents' Council is comprised of the ten (10) immediate past presidents not currently serving on the Board of Trustees. The Past Presidents' Council's primary responsibility is the selection of the Honorary President as well as the recipients of all MPhA scholarships and awards.

This year, the Past Presidents Council sent a notice and application for MPhA's scholarships to each MPhA/ASP student member. After reviewing the more than 30 applications, the Council selected three pharmacy students to receive \$500 PEP scholarships. These scholarships, coming from the funds contributed by members, are to be used by the student to assist them during the months that they are doing PEP rotations and unable to work. The pharmacy students selected this year were: Anthony Guerra, Gina McKnight, and Constantine Markos. The Council also selected Deborah Sharkey to receive the 1995 Harry Kaufman Award for outstanding community service by a pharmacy student.

The Council was also charged with reviewing the nominations submitted for the MPhA awards. These awards include: Seidman Distinguished Achievement Award, Marion Merrell Dow Young Pharmacists Award, Dupont Innovative Practice Award, Wyeth-Ayerst Bowl of Hygeia, and the MPhA Honorary President.

Unfortunately, hardly any nominations were received despite distribution in both the MPhA newsletter and *The Maryland Pharmacist*. The Council, with input and advice from the Board of Trustees, spent considerable time researching and selecting pharmacists truly deserving of these awards. Pharmacists are encouraged to nominate their colleagues for these important honors.



Nominating Committee

Chair: Jim Tristani, P.D.

The MPhA Nominating Committee is responsible for selecting the candidates for the upcoming vacancies on the Board of Trustees, the officer positions of President-Elect, Vice-President, and Treasurer. Also, the Nominating Committee is responsible for coordinating and overseeing the process for selecting three candidates for each seat on the Maryland State Board of Pharmacy.

The Nominating Committee presented the following slate of candidates to the MPhA Board of Trustees during their meeting on February 16, 1995. This slate was subsequently approved by the House of Delegates during the MPhA Mid-Year Meeting on February 26, 1995, in Annapolis.

The slate was, for President Elect, Ernest Testerman and Ellen Yankellow; for Vice-President, Alisa Billington and Jean Freels; for Treasurer, Martin Yankellow and Ronald Sanford. Four positions for the MPhA Board of Trustees were open for election in 1995. The slate for these three-year terms were: Seat #1, Abigail Lagman and Tim Lubin; Seat #2, Irving Lottier and Robert Martin; Seat #3, Murhl Flowers and Joseph Marrocco; Seat #4, Doug Haggerty and Phillip Marsiglia.

Maryland law requires that MPhA provide three nominees for each upcoming vacancy on the Maryland State Board of Pharmacy. Eight pharmacists were nominated to replace Steven Cohen. These candidates were: Phyllis Bartilucci, Morrell Delcher, E. Robert Feroli, Janet Getzey-Hart, David Knauer, W. Irving Lottier, Raymond Morris, and Jacob Raitt.

The list of eight candidates was sent to the entire pharmacy community in the March issue of *The Maryland Pharmacist*. The returned ballots were tallied on April 7. E. Robert Feroli, W. Irving Lottier, and David Knauer were the three pharmacists selected for recommendation to the Governor for appointment.



Member Services Committee

Chair: Ellen Yankellow

Instead of having a formal committee structure this year, the Member Services Committee was basically comprised of myself, the staff and a few pharmacists whose input I used on an as needed basis. We had two major priorities this year -- to increase the number of services available to current members and to identify targeted methods for attracting new members to the organization.

The Board of Trustees approved at least eight new services during the course of the 1994-1995 Association year. These included complimentary continuing education programs through the monthly journal, a discount car-rental service from Alamo, a discount long-distance

program with AT&T, discounts through the PharmArt catalog, honorary certificates signed by the Board of Pharmacy and Board of Trustees for retired members, discounts off of national association dues for reciprocal memberships, ACPE accreditation of continuing education journal articles, and the first in a series of free two-credit continuing education booklets. MPhA has received a great deal of positive feedback on these new benefits and we encourage all of our members to suggest new ways we can improve the value of belonging to the Association.

The second responsibility for this Committee was to identify and promote membership to non-members. We accomplished this in two ways. First, the Board of Trustees authorized the distribution of *The Maryland Pharmacist* to every pharmacist in the state as an experiment. This began in January 1995 and will continue through August. Membership solicitation, as well as promotion of MPhA continuing education activities, has been somewhat successful. The June issue of the journal was a major promotional to the non-member pharmacists. The impact of that solicitation will not be able to be evaluated for at least several weeks. In addition to this massive promotion, MPhA also sent targeted personal letters to all members who had not renewed their 1995 memberships. This has helped retain our members despite the first dues increase since 1985.

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One additional positive for 1995, MPhA's January trip through the Panama Canal, coordinated by Past President Elwin Alpern and Towson Travel, resulted in a \$1,500+ income to the Association.



Professional Issues Committee

Chair: Beverly Yachmetz

The Professional Issues Committee was formed in 1992. The purpose of the Committee is to assist the Board of Trustees and staff in forming responses to various statewide or national activities or queries that pertain to pharmacy practice. The Committee is comprised of pharmacists from all areas of practice and geographic location. While the Committee does not actually meet, the members are responsible for reviewing a great deal of material and quickly returning their comments to the offices.

This year, the Committee tackled three issues on behalf of the Board. The first was to review and formulate MPhA's response to the draft "Inpatient Institution Regulations (10.34.03)" promulgated and distributed by the Board of

Pharmacy in mid-summer 1994. Our response to these regulations was lengthy and resulted in a number of changes to the draft. Additionally, MPhA and MSHP worked very closely to ensure that the final regulations would reflect current and future practice in inpatient settings.

The second issue upon which the Professional Issues Committee lent assistance was in the analysis of a document entitled "Pharmaceutical Care Benefit Principles" that was provided to MPhA by the American Pharmaceutical Association in the fall of 1994. This evaluation resulted in three pages of comments from our Committee members that were subsequently sent to the APhA headquarters. Because of our Committee's efforts, Maryland was one of the few states who responded with comments.

The last issue that the Professional Issues Committee dealt with this year was an ongoing assessment and refinement of the "Long Term Care Regulations (10.34.23)" promulgated by the Board of Pharmacy. The Committee provided initial comments to the Board of Trustees in early 1994. These comments were incorporated into the regulations almost verbatim when the October 1994 draft was circulated. We again reviewed the regulations, found them satisfactory, and commented so to the Board of Trustees. Both sets of regulations (institutional inpatient and long-term care) are now on their way through the Department of Health and Mental Hygiene's regulation approval process.



Finance and Budget Committee

Chair: Ronald Sanford

Faced with a fairly static revenue and increasing expenses, the Finance and Budget Committee started the year with the difficult task of reviewing MPhA's largest income source -- member paid dues. The last dues increase was in 1985 and the ten year lag made itself evident in the Association's cash flow and ability to put monies away for the future during the past three financial years. In September and October, the Committee and the Board of Trustees reviewed each of the membership categories, evaluated the current dues levels, and projected what the impact on membership would be in each of those categories.

The dues increase, which varied by category, went into effect for the 1995 Association year. Fortunately, our estimate of a 10% reduction in membership because of the increase was unfounded. In fact, membership will exceed 1994 figures even with the dues increase. I believe that is a testament to the commitment of Maryland pharmacists and a recognition of MPhA's activities and benefits on their behalf.

The Committee met in late October to formulate a stringent spending program for the organization. Our 1995 budget included reductions in a number of expense areas and an increase in income projections -- a challenge for the Board and our staff. In May, the Finance and Budget Committee met again to assess the first quarter and to determine whether any corrections needed to be made for the second and third quarters.

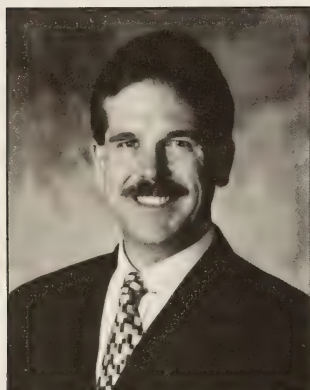
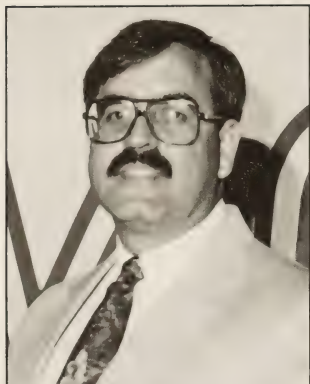
Examining the new computerized financial reports that staff developed, the Committee found that income was over projected and expenses were well-in line with budgeted figures. Only two areas presented major concerns. The first was that the leases and staff salary offset from the Mid-Atlantic DUR corporation were in jeopardy for the third and fourth quarters of 1995. This is because the major contract held by Mid-Atlantic DUR, MPhA's for profit subsidiary, will be suspended for up to six months while a new contract bid is developed by the Medicaid department.

The Committee, working with staff, developed two recommendations to immediately reduce staff expenses by restructuring DUR personnel from full-time to part-time employees. This was done at the employees' suggestion and I commend their willingness to preserve the organization's financial well-being.

The second area examined by the Committee was the increase expense of printing and distributing *The Maryland Pharmacist* to all pharmacists in Maryland. Planned by the Board as a means to promote membership and to obtain additional advertisers, this added expense has created an interesting and difficult balance between the solicitation of members and maintaining a reasonable journal budget. The Committee recommended that the mass mailing be re-reviewed in mid-August during the second-quarter review and a decision be made at that point whether or not to continue the mailings. A major factor in our decision will be the results of a June 1995 membership promotion that accompanied the journal.

Just as the typical pharmacy is faced with financial challenges, so to is MPhA. Our ability to remain financially sound rests with the continued support and cooperation of the Board of Trustees, our staff, and the pharmacy and pharmacist community.





Health Care Policy and Legislation Committee

Co-Chairs: Phillip Marsiglia and Ernest Testerman

As reported in the June, 1995 issue of *The Maryland Pharmacist*, this year's legislative session provided a number of challenges to the Health Care Policy and Legislation Committee (a merger this year of the Legislative Committee and the Third-Party Committee). There were four legislative priorities for the organization this year: 1) securing passage

of a patient access/freedom of choice act, 2) securing passage of equal access to pharmaceutical manufacturers discount legislation, 3) obtaining clarifications of the Board of Pharmacy nominating procedures through an amendment to the Pharmacy Practice Act, and 4) providing funding to the Pharmacists Rehabilitation Committee through the Board of Pharmacy. In addition to these, and several other major issues, the Committee was also charged with monitoring all legislation and regulations that could either positively or negatively impact on the profession.

Two major events that occurred during 1995 will require substantial volunteer and financial resources by MPhA over the next year. The first is the current plan by the Maryland Medical Assistance Program to reduce the pharmacy dispensing fee by a total of \$1.8 million during the next fiscal year. Emergency regulations to reduce the dispensing fee by approximately 40 cents per prescription are pending. MPhA will testify before the Administrative, Executive and Legislative Reference Committee (AELR) about the impact that these reductions will have on the typical Medicaid provider.

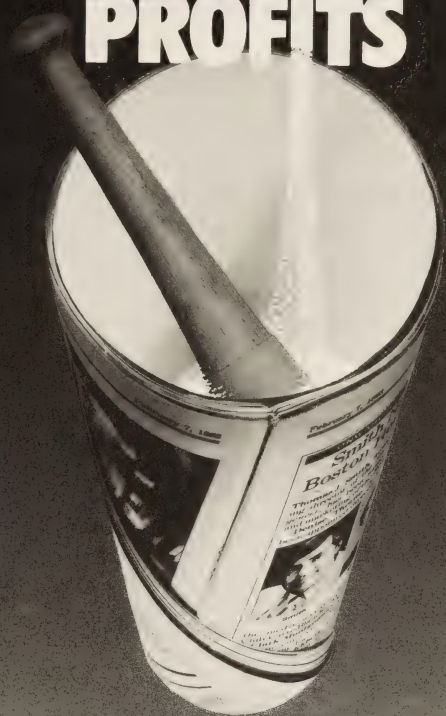
The second development centers around the State's plan to seek and obtain a HCFA 1115 waiver to "experiment" with the delivery of medical services to Medicaid recipients. Other states who have obtained such waivers have generally sought to

mandatorily enroll all Medicaid patients into a managed care or HMO plan. This could effectively challenge the profession by eliminating some or all pharmacy providers. While the HCFA waiver application process is just beginning, MPhA has already sought the cooperation of many major pharmacy providers in putting together a proposal to "carve out" the pharmacy benefit. We believe that such a "carve out" would enable the State to maximize its financial benefits by retaining OBRA '90 pharmaceutical discounts from manufacturers and to obtain the continued benefits of both a prospective and retrospective drug utilization review program. While the benefits of a "carve out" will undoubtedly have a short term benefit for pharmacy, we must be vigilant to ensure that long term benefits of payment for cognitive services and pharmaceutical care are both recognized and included in future Medicaid reimbursement calculations.

There is a great deal that remains to be accomplished by this Committee. The Pharmaceutical Care Committee's initial steps towards reviewing and revising the Pharmacy Practice Act to expand our scope of practice will require a great deal of grassroots lobbying and support. However, given the past overwhelming and enthusiastic dedication of our members and the pharmacy community, we are confident that we will be successful.

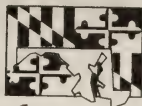
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A New Frontier for Pharmacy

Resolutions Adopted by MPhA's House of Delegates

*Mark Sanford, P.D., Chairman
House Resolutions Committee*

Each year, the MPhA House of Delegates convenes during the Annual Convention to review and debate member submitted resolutions. These resolutions are the basis for policy statements and positions of the organization. In short, these resolutions help us chart the future direction of the Association.

This year, 10 resolutions were considered during the House's Second General Business Session on Tuesday, June 21, 1995. The following seven resolutions were formally adopted.

Employee Pharmacists and Workload Issues

Whereas, an increasing number of pharmacist dispensing errors have been reported by the lay and professional press; and,

Whereas, these reported errors were, in many cases, directly attributable to a working environment that discouraged pharmacist/patient interaction and/or were based on turning out high numbers of prescriptions in a short period of time without adequate professional or technical staffing; and,

Whereas, many of these errors could have been prevented had the pharmacist been given sufficient time and encouragement to perform pharmaceutical care and patient counseling services;

Therefore, be it resolved that, the Maryland Pharmacists Association encourages and will work with both pharmacy employers and employees to reassess the current method of delivering prescription services so as to maximize professional opportunities for the provision of pharmaceutical care and patient counseling; and,

Be it further resolved that, the Maryland Pharmacists Association opposes any attempt by an employer to establish, use, or implement prescription quota systems for the purposes of employee pharmacist retention, discipline, advancement, or dismissal; and,

Be it further resolved that, the Maryland Pharmacists Association shall assist employee pharmacists in filing complaints with the Maryland State Board of Pharmacy against any pharmacy permit holder whose workload policies -- including but not limited to staffing, prescription volumes, prescription quotas, work hours, meal times and breaks -- jeopardize the safety of patients.

Confusing OTC Labeling

Whereas, more manufacturers of over-the-counter products are capitalizing on established name recognition by marketing "families" of products under that established name; and,

Whereas, product names such as Anacin (long recognized as a combination of aspirin and caffeine), Bayer (aspirin), Benadryl (diphenhydramine) are now being marketed over combinations of ingredients that contain no aspirin and caffeine (Anacin-Free), no aspirin (Bayer Select), and no diphenhydramine (Benadryl cough syrups); and,

Ethical Dilemmas and Rights of Pharmacists

Whereas, this practice causes substantial confusion among consumers and pharmacists that is not in the best interest of good self-medication;

Therefore, be it resolved that the Maryland Pharmacists Association denounces the use of recognized brand names of over-the-counter medications for the purposes of marketing other combinations of products that are totally unrelated to the original branded product; and,

Be it further resolved that the Maryland Pharmacists Association encourages the profession to report incidences of these confusing product names to the MPhA offices, and,

Be it further resolved that the Maryland Pharmacist Association shall file a formal request for review of these and similar products with the United States Pharmacopeial Convention, Inc., the United States Food and Drug Administration, and the US Federal Trade Commission; and,

Be it further resolved that the Maryland Pharmacists Association shall introduce resolutions on this issue to the American Pharmaceutical Association and the National Association of Retail Druggists to bring greater attention to this problem.

Whereas, situations where drugs and pharmaceuticals are used prescribed for abortions, executions, assisted suicide, and euthanasia are ones that pharmacists may face during their professional career; and,

Whereas, the dispensing of certain pharmaceuticals can and does cause conflicts between either legal or medical considerations and the ethical or religious beliefs of individual pharmacists; and,

Whereas, the balance between the professional obligations to cause no harm to a patient, the personal beliefs of a pharmacist, and the interests of society is varies with each individual case;

Therefore, be it resolved that the Maryland Pharmacists Association neither endorses or opposes the use of pharmaceuticals, drugs or chemicals in the performance of abortions, executions, euthanasia, or assisted suicide; and,

Be it further resolved that the Maryland Pharmacists Association believes that it is the fundamental professional and personal right of an individual pharmacist to determine whether he or she chooses to dispense or not dispense medications in these and similar situations; and,

Be it further resolved that the Maryland Pharmacists Association opposes any attempt by an employer or fellow pharmacist to impose their professional or personal beliefs on another pharmacist for the purposes for requiring that a prescription be dispensed.

Maryland Poison Center

Whereas, the Maryland Poison Center provides both vital emergency services for thousands of Maryland residents around the clock and poison prevention and education programs; and,

Whereas, the Maryland Poison Center is funded primarily through the State of Maryland's higher education budget and is not funded at a level which enables it to provide necessary poison emergency and prevention services throughout the state; and,

Whereas, poison prevention and treatment is a public health matter and an issue in which pharmacists have played a leading role and have been identified with its success;



Therefore, be it resolved, that the Maryland Pharmacists Association supports efforts to provide funding for the Maryland Poison Center through the Department of Health and Mental Hygiene at a level which will enable the Center to provide poison emergency and prevention services for the entire State of Maryland, for the health and welfare of its citizens.

Reciprocity Examinations for Licensure

Whereas, all pharmacists who take the State Board of Pharmacy licensure examination in Maryland are required to take and pass a written state law examination; and,

Whereas, those pharmacists reciprocating to Maryland are not currently required to take or pass a written state law examination; and,

Whereas, all pharmacists practicing in Maryland are required to practice under the same set of laws regardless of the nature of their pharmacy license,

Therefore, be it resolved that the Maryland Pharmacists Association recommends that the Maryland State Board of Pharmacy require all candidates for reciprocity in Maryland to take and pass a graded, written examination of Maryland pharmacy law.

Sales of OTC Products in Non-Pharmacy Locations

Whereas, the ever expanding numbers of "dollar" stores and other discounters are evident throughout the state; and,

Whereas, much of the merchandise sold by these outlets is oftentimes classified as discontinued or odd lots; and,

Whereas, dated over-the-counter internal and external medications are commonplace in these establishments and it is evident from viewing the packaging that many of these drug products offered for sale are clearly out-of-date and pose a threat to the health and welfare of the citizens of Maryland; and,

Whereas, any establishment selling "food" products in Maryland must be licensed to sell food by the State, even if the food products are only candy bars;

Therefore, be it resolved that the Maryland Pharmacists Association shall seek legislation or regulations that require all non-pharmacy sellers of over-the-counter medications to be licensed for the sale of these products; and,

Be it further resolved that to demonstrate the extent of this problem, the Maryland Pharmacists Association shall coordinate a purchase campaign with its membership to obtain evidence of the sale of expired, improperly stored, or other threats to public safety to show to representatives of the State, the Department of Health and Mental Hygiene, and legislators.

Pharmacy Technicians Recognition and Regulation

Whereas, it is an inherent right of a profession to educate, recognize, employ and utilize supportive personnel in the performance of technical tasks related to the profession; and,

Whereas, the Maryland State Board of Pharmacy, the governmental agency that regulates the profession and protects the consumers of Maryland, has traditionally taken the position that oversight of pharmacy technicians and pharmacy supportive personnel are the purview of pharmacists and has also declined to propose or approve regulations that mention pharmacy technicians and pharmacy supportive personnel,

Therefore, be it resolved, the Maryland Pharmacists Association believes the responsibility of recognizing, educating, and regulating pharmacy supportive personnel or pharmacy technicians belongs to individual pharmacists, pharmacy permit holders and professional pharmacy organizations; and,

Be it further resolved, the Maryland Pharmacists Association shall oppose any effort by governmental agencies to certify, license or otherwise formally recognize pharmacy supportive personnel or pharmacy technicians; and,

Be it further resolved, that the Maryland Pharmacists Association shall oppose any effort by governmental agencies to regulate or otherwise dictate how pharmacy supportive personnel or pharmacy technicians shall be used in a pharmacy setting.

MP



Computerized Order Control

At Bergen Brunswig's Richmond Regional Distribution Center, orders are controlled and monitored by a unique computer system. The control station, pictured above, assigns a bar-coded shipping "tote" to each order. The computer is programmed with the location of every product and content of each order and routes the tote to all items requested. The result? Faster order processing with 99.9% accuracy!



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Supporting the Profession

Profiles of Pharmacists and the Industry

This Month: Searle

Searle is well known as the manufacturer and marketer of many vital medications: Ambien, Daypro, Cytotec, and Calan SR to name a few. For pharmacists, the Searle name carries a reputation for quality products and services based on more than 100 years in the pharmaceutical industry.

Today, Searle's goal is to continue to develop and manufacture high quality medications. However, a new Searle strategy is unfolding as well -- to increase its ability to provide health care solutions for its business partners, including its retail distribution associates.

Searle recognizes that pharmaceutical care, the pharmacist's ability to enhance the therapeutic outcomes of their patients, is a health care component that's difficult to measure but essential for the well being of the patient.

Searle understands the growing role of the pharmacist in the total health care of today's Americans. The ability to distribute medication, while often thought of as the primary role of the pharmacist, is now viewed as a portion of the total pharmacy experience. More often than not, the pharmacist is called upon as a trusted advisor and counselor. As these duties continue to expand, Searle has partnered with pharmacists to develop training and recognition for the increasing responsibilities tied to the profession.

Drug Therapy

Many patients voice concerns to their pharmacists about their medication, especially questions that occur to them after they have left the physician's office. In an effort to provide relevant information to help pharmacists answer consumer inquiries, Searle has developed a series of educational programs for its leading products specially designed for the pharmacist's use.

For example, in Maryland, Searle sponsored quarterly lectures allowing pharmacists to hear directly from physicians on issues such as the uses of non-sterodials for pain or inflammation. And Searle's insomnia program for pharmacists highlights the many attributes of treating insomnia to help pharmacists counsel patients on obtaining quality sleep.

Measuring Value

While expert advice from pharmacist at the point-of-purchase is invaluable to consumers, its intangible nature makes this pharmacy function difficult to measure.

As the partnership between pharmacists and other health care organizations grows closer with each pass of the legislative pen, Searle has taken the lead in helping pharmacy develop strategies to capitalize on new laws effecting the pharmaceutical industry.

According to Maryland law, a statutory provision exists for insurers and HMOs to compensate health professionals (including pharmacists) who are authorized to provide medical services as indicated in the state's Health Occupations Article. Clearly, training and education was needed to explain the new process of billing for services and to help pharmacists place value on the services they provide.

That's the premise for Searle's sponsorship of a statewide program entitled *DOCU 101: An Elementary Course in Documentation, Billing, and Reimbursement of Pharmacists Services*. The Searle funded course is co-sponsored and administered by the MPhA. The series of classes leads pharmacists through the process of filling out the NARD Pharmacist Claim Forms, HCFA 1500 forms as well as the use of ICD-9 and CPT treatment codes.

The Annual BMPPA Awards Banquet and Dinner Dance



A Change of Season

*Saturday, October 28, 1995
Sheraton Towson Hotel*

Classes will be closely monitored for effectiveness by the MPhA, results Searle is eager to evaluate. The program will also serve as a prototype for other states. Searle and the MPhA plan to develop a "how to" guide to allow additional states to benefit from Maryland's experience.

Dates and times for the first of these classes will be distributed to MPhA members in September. Currently, ten different classes will be held throughout the state so there's sure to be one close to you.

Please contact your local Searle Representative to find out more about these and other Searle sponsored programs. MP



1994-95 MPbA President Arnold Davidov thanks Searle's Penney Miller and Norman Rosenzweig for the support.

This lesson reviews several new drugs recently introduced to the US pharmaceutical market for the treatment of allergic rhinitis.

Allergic rhinitis (hay fever) results from inflammation of the mucous membranes that line the inside of the nose. While it can appear at any age, it usually begins during childhood. Attacks strike at any time of the year (perennial) or during periods when the pollen count is high (seasonal).

The early and mild symptoms of allergic rhinitis include itching, increased secretion of fluid from the nasal mucosa (rhinorrhea), sneezing, watery and sore eyes, irritability and fatigue. Serious cases involve episodes of violent

sneezing and total obstruction of the nasal passages due to production of increased mucus secretions.

Allergic rhinitis can lead to secondary inflammation of the facial sinuses, sinus headache, postnasal drainage, continual nasal stuffiness, and sinus infections.

Acrivastine

Trade Name: Semprex-D

Acrivastine {Ack-ri-VAST-een} (ingredient in Semprex-D) is a new histamine₁ (H₁) receptor antagonist that is an analog of triprolidine (the antihistamine in actifed). Its potency is also similar to triprolidine. Combined with the sympathomimetic amine pseudoephedrine, the new product (Semprex-D) is indicated for relief of symptoms associated with seasonal allergic rhinitis, which reportedly affects 22 million Americans.

The mechanism of action of acrivastine is similar to other antihistamines. It binds competitively to H₁ receptors to block histamine action. The outcome is reduced physiologic response to histamine.

For treating allergic rhinitis, antihistamines are more effective when taken early in the season when pollen counts are low. Later, as pollen concentration increases and allergy-induced histamine is excessive, the action of antihistamines may be overwhelmed, and their pharmacologic effect is inadequate to block histamine action on H₁ receptors.

To be effective, antihistamines must enter into and combine with histamine-specific receptors on the membranes of cells sensitive to its stimulation. This is a dynamic, ever-changing condition with antihistamine competing with histamine for the same receptor sites. Relative concentrations of each determine which action predominates. If the antihistamine is present in high enough concentration when the initial surge of histamine is released by the allergic response, symptoms should be reduced.

Drowsiness is the most common adverse effect, although it is reported less often than with first-generation antihistamines. In premarketing trials, drowsiness occurred in nine percent of acrivastine-treated patients and three percent of those

Antiallergy Agents

| Generic | Trade Name | Availability | Dosage Regimen |
|-------------------------------------|-------------------|--|---|
| Acrivastine (w/ pseudoephedrine) | Semprex-D | capsules (8mg acrivastine, 60mg pseudoephedrine) | 1 capsule every 6 to 8 hours |
| Levocabastine | Livostin | eye drops 0.05% | 1 drop in eye QID for up to 2 weeks |
| Lodoxamide | Alomide | eye drops 0.1% | 1-2 drops in eye QID for up to 3 months |
| Budesonide | Rhinocort | aerosol canister, 32 mcg/actuation | 256 mcg/day in divided doses |
| Fluticasone | Flonase | glass bottles, 50 mcg/actuation | up to 200 mcg/day in divided doses |

Table 1

receiving placebo. One reason for its reduced CNS depressant action is that it contains a polar acrylic chain on its basic molecule. This reduces its lipophilicity (fat solubility). Its manufacturer requested the nonsedating classification for acrivastine so it could compete with Claritin, Hismanal, and Seldane, but was denied. Instead, the manufacturer granted Adams Labs the right to market Semprex-D.

Acrivastine, in combination with pseudoephedrine, is effective in treatment of seasonal and perennial allergic rhinitis one hour after administration. Whether this combination has advantages over previously available products in its class is yet to be determined. Information that can be used in counseling patients on Semprex-D is listed in Table 2.

Levocabastine

Trade Name: Livostin

Levocabastine {Levo-cab-AST-een} (Livostin-LEE-vo-Stin) is an ophthalmologically administered histamine antagonist that is specific for histamine H_1 receptors. It is indicated for the treatment of symptoms of allergic conjunctivitis. Unlike most other products for conjunctivitis that contain a decongestant or corticosteroid, Livostin does not. This makes it the first single-entity histamine eyedrop approved by the FDA since the DESI review in the 1970's.

New Drugs Review: Antiallergy Agents

*Thomas A. Gossel, R.Ph., Ph.D., Dean
Ohio Northern University*

*J. Richard Wuest, R.Ph., Pharm.D.
Professor of Pharmacy Practice, University of Cincinnati*

A professional development program made possible by an educational grant from **SEARLE**.

Conjunctivitis refers to an excess of blood in the membranes lining the eyelid. It is usually caused by reactions to allergens such as pollen.

Levocabastine is structurally dissimilar from other antihistamines, but it has not been marketed as a systemic product.

Levocabastine acts quickly, with relief possible within a few minutes of application. All symptoms of conjunctivitis, not just itching, are relieved.

Levocabastine has a low order of adverse reactions. The most frequently observed adverse effect reported is mild, transient stinging and burning of the eyes in about 15 percent of patients. Headache was reported by 5 percent of patients in clinical trials but no other adverse drug reactions were seen above the 3 percent level.

Patients using Livostin ophthalmic suspension should be advised to shake the container well before instilling the drops. Patients may experience transient burning or stinging upon instillation of the drops. Its manufacturer states that if these symptoms persist, the patient should be advised to contact the doctor. Other information that can be used to counsel patients is listed in Table 3.

Lodoxamide

Trade Name: Alomide

A mast cell stabilizer, lodoxamide {low-Dox-a-mide} prevents degranulation of mast cells' subsequent release of histamine and other inflammatory mediators, thus preventing hypersensitivity reactions in the eye. Lodoxamide is indicated for treatment of vernal keratoconjunctivitis, vernal conjunctivitis, and vernal keratitis.

Patient Counseling for Semprex-D

Semprex-D is used to relieve the runny nose, watery eyes, sneezing and stuffiness of hay fever and other upper respiratory allergies and conditions as determined by your doctor.

Take the capsules with a full glass of water. If they upset your stomach, you may take them with food.

Some people may experience dizziness, blurred vision, or drowsiness from this medication. If you do, be careful driving or performing hazardous tasks. Alcoholic beverages can increase the drowsiness effect.

Some people may experience dry mouth. If you do, suck on hard candy, chew gum or use a saliva substitute.

Do not take nonprescription cough/cold, asthma, hayfever, sleep aid, or diet medications without asking your doctor or pharmacist.

Semprex-D may make your skin more sensitive to sunlight or sunlamps. Ask your pharmacist about a suitable sunblock product (of at least SPF 15) to reduce exposure problems.

If you miss a dose of Semprex-D, take it as soon as possible. But, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose, unless directed by your doctor.

Every medication is capable of producing side effects. Most patients experience few or no problems while taking Semprex-D. However, be sure to tell your doctor if the following occur: drowsiness, blurred vision, dry mouth, headache, mental confusion, loss of appetite, nervousness, chest pain, irregular heartbeat, or any other unusual, bothersome effects.

Table 2

Vernal conjunctivitis is a severe form of non-infectious allergic conjunctivitis. It is characterized by seasonal exacerbations of swelling and irritation of the conjunctiva, thought to be caused by allergens. Vernal keratitis is a chronic inflammation of the cornea. Keratoconjunctivitis is a combination of these two events. The conditions may be triggered in susceptible individuals by airborne allergens. Irritation from contact lenses may also trigger them. They occur more often in children and young adults than in older adults.

To briefly review what happens in these inflammatory conditions, it is estimated that each eye contains 50 million mast cells. These are concentrated on the outer ocular surface. Within each mast cell are up to several hundred granules that contain preformed chemical mediators (e.g., prostaglandins, leukotrienes). Mast cells can attach one of the antibody types (IgE) to their cell membrane.

Subsequent exposure to an offending allergen (antigen) results in combination of antigen with antibody (IgE) on mast cell membranes. In this reaction, the antigen is attracted to an IgE molecule that is bound to the membrane. With repeated exposure to antigen, a cascade release of the mediators is initiated.

These, in turn, increase conjunctival vascular permeability and allow blood cells responsible for the inflammatory response to infiltrate the area. This triggers immediate and late-phase inflammatory reactions. These reactions are characterized as Type 1 hypersensitivity responses (itching, redness, tearing, conjunctival changes, vascularization, or plaque formation) in the cornea.

Lodoxamide blocks Type 1 immediate hypersensitivity reactions. It inhibits the increased vascular permeability associated with IgE and antigen-mediated reactions. It has no intrinsic antihistaminic, vasoconstrictor, or anti-inflammatory action, and does not block cyclooxygenase as do the prostaglandin inhibitors. While its precise mechanism is unknown, one hypothesis is that lodoxamide blocks calcium entry into mast cells following antigen stimulation. This stabilizes cell membranes and inhibits degranulation and release of inflammatory mediators.

Transient burning, stinging, and ocular discomfort were reported in up to 15 percent of patients in clinical trials. Other responses include blurred vision, dry eyes, tearing, ocular itching, hyperemia (tissue swelling due to engorgement of blood) crystalline deposits, and foreign body sensation. These are experienced in one to five percent of patients. Antihistamines and corticosteroids have been main-stay treatments for symptoms of vernal keratoconjunctivitis because the symptom is self-limiting. Antihistamines alone are only partially

Continuing Education

Goals

The goals of this lesson are to identify and discuss the actions and reactions of three new drugs introduced into therapy during 1994-95.

Objectives

At the conclusion of this lesson, successful participants should be able to:

1. exhibit knowledge of the pharmacologic classification and therapeutic considerations for the drugs discussed;
2. select from a list, the indications, mechanisms of action, benefits and limitations of the drugs presented;
3. identify adverse effects, major toxicities, and drug interactions associated with these products; and,
4. demonstrate an ability to counsel patients on the drugs reviewed.



This program has been approved for one credit hour (0.1 CEUs) of ACPE approved continuing education. The Maryland Continuing Education Coordinating Council is an approved provider for continuing education programs for pharmacists by the American Council on Pharmaceutical Education. ACPE # 186-144-95-027-H01.

The benefit of mast cell stabilization is that it provides the benefit of anti-inflammatory action of a corticosteroid and the antiallergic effect of an antihistamine with fewer side effects. Studies confirm that lodoxamide is at least as potent as cromolyn in relieving symptoms of vernal conjunctivitis. If the manufacturing problems with Opticrom can be resolved to the FDA's satisfaction, it may then return to the market. Nedocromil (Tilade aerosol inhaler) is another mast cell stabilizer that is undergoing clinical evaluation in the U.S. as an ophthalmic solution for this use.

Information that can be used in counseling patients is listed in Table 3.

Budesonide

Trade Name: *Rhinocort*

Fluticasone

Trade Name: *Flonase*

Budesonide {Boo-DES-o-nide} (Rhinocort: RHINE-o-cort) is a corticosteroid that has a high level of local anti-inflammatory action compared to systemic activity. Administered intranasally, budesonide is approved for treatment of seasonal and perennial allergic rhinitis in patients six years of age and older.

A medium-potency topical corticosteroid, fluticasone {FLUTE-ic-a-sone} (Flonase: FLOW-nace) is approved for treatment of seasonal and perennial allergic rhinitis in patients 12 years of age and older. It is the first intranasal product approved for administration in once daily doses. Fluticasone cream and ointment dosage forms (Cutivate) are also available for topical treatment of dermatoses. An inhalation dosage form is in clinical trial for treating asthma, and oral tablets are being studied for use in treating Crohn's disease.

The precise mechanism of action of budesonide and fluticasone in relieving symptoms of allergic rhinitis is unknown. The current theory is that they most likely work by inhibiting release of mediators of inflammation. These mediators include histamine, leukotrienes, and cytokines.

Patient Counseling for Alomide and Livostin

The following is one method for administering Alomide and Livostin eye drops. If your doctor told you another way or if printed instructions were supplied with the prescription, follow those instructions.

- * Wash your hands with soap and water before using the eye drops.
- * Gently pull the lower eyelid downward to form a pouch. Tilt your head backward, hold the dropper above the eye, and drop the prescribed amount inside the lower lid. Do not touch the dropper to any surface.
- * Release your lower lid. Try not to blink for a few seconds. Replace the cap on the bottle. *Never* rinse the dropper. You may contaminate the medication.

Eye drops may blur your vision for a few minutes. If they do, do not drive or perform hazardous tasks until your vision has cleared. *Never* use eye drops that have changed color or appear to have crystals in the liquid. Call your doctor if your condition becomes worse or if you experience itching or burning for more than a few minutes after placing drops in the eye. If you are using more than one kind of eye drop at the same time, wait at least 5 minutes before you use another eye drop. Check with your doctor or pharmacist about which one to use first. If you wear contact lenses, remove them before instilling the eye drops. If you miss a dose, use it as soon as possible. But if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not use a double dose unless directed by your doctor. Most eye drops should be kept at room temperature unless otherwise instructed by your doctor or pharmacist. Keep this medication in its original, labeled container and out of reach of children. Do not keep or use outdated medication. Every medication is capable of producing side effects. Most patients experience few or no problems while using these eye drops. However, be sure to tell your doctor if you experience any unusual bothersome effects.

Table 3

Used correctly, these agents impart antiinflammatory activity with minimal systemic effects. However, exceeding the recommended dose opens the door for systemic toxicity, including hypothalamic-pituitary-adrenal (HPA) function suppression.

Side effects are similar to other widely used prescription nasal sprays. Those whose incidence is in the 3 to 4 percent range are nasal irritation, pharyngitis, cough, nose bleed and dry mouth.

Both of these agents are longer acting and have fewer systemic effects than previously available nasal corticosteroids.

Patients using Rhinocort and Flonase should be advised to use the inhaler units exactly as prescribed. The patient information leaflet in the package should be provided and explained to the patient. Patients should inform their physician if symptoms persist or worsen. Patients who are on corticosteroids such as Rhinocort and Flonase should be warned to avoid exposure to chickenpox or measles. They should inform their doctor if they are exposed. Additional counseling information is included in Table 4. **MP**

Tables 2, 3, and 4 are adapted from the Pharmex PALS (patient advisory leaflets). For more information, call (800) 233-0585.

Patient Counseling for Rhinocort

Rhinocort is used to relieve or prevent the discomfort of seasonal allergies or other conditions as determined by your doctor. The following is one method for administering Rhinocort:

Open the nasal adapter by pressing on the arrow on the light gray part of the unit. Turn the light gray part into the dark gray part until it clicks locked. Shake the canister well before using it. Gently blow your nose just before using this medication. Close one nostril with your finger and carefully insert the nasal applicator into the open nostril. Hold your breath and press firmly on the canister with your finger, while using your thumb on the base for support. Repeat in other nostril. Close the unit by pressing under the tube on the light gray part. Turn it into the dust cover until it clicks. To help prevent contamination, rinse the applicator in warm water after each use or at least weekly.

The manufacturer states that Rhinocort is to be used within 6 months of opening the aluminum pouch. After the pouch is opened, the unit should not be stored in high humidity. Keep this medication at room temperature out of the reach of children. In case of accidental ingestion or overdose, call your doctor or poison control center immediately. Do not keep or use outdated medication. Most patients experience few or no problems while using Rhinocort. However, be sure to tell your doctor if the following occur: continued nasal irritation; excessive sneezing; bloody discharge from the nose; persistent sore throat; swelling of the face, hands or feet; skin rash; difficulty in breathing; muscle cramps or pain; or any other unusual bothersome effects.

Patient Information for Flonase

Flonase is used to relieve or prevent the discomfort of hay fever and other nasal problems as determined by your doctor. The following is one method for administering Flonase:

Shake the bottle gently and remove the dust cover. The first time it is used, the pump must be primed by holding your forefinger and middle finger on either side of the nasal applicator and your thumb underneath the bottle. Point the nasal applicator away from you and press down on the pump 3 or 4 times until a fine spray appears. This may be repeated if you have not used the pump for a week or more. Gently blow your nose just before using Flonase. Close one nostril with your finger, tilt head slightly forward and carefully insert the nasal applicator into the open nostril. While breathing through your nose, press downward firmly using your forefinger and middle finger, while using your thumb on the base of the bottle for support. Breathe out through your mouth. If a second dose is prescribed, repeat. Then apply in your other nostril. Wipe the nasal applicator with a clean tissue and replace the dust cover.

Do not skip a dose, change the amount, or stop using it without consulting your doctor. It may take several days to notice improvement. If you miss a dose, use it as soon as possible. But, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not use a double dose, unless directed by your doctor. Keep this medication at room temperature out of the reach of children. In case of accidental ingestion or overdose, call your doctor or poison control center immediately. Do not keep or use outdated medication. Most patients experience few or no problems while using Flonase. However, be sure to tell your doctor if the following occur: continued nasal irritation; excessive sneezing; bloody discharge from nose; persistent sore throat; swelling of the face, hands, or feet; skin rash; difficulty in breathing; muscle cramps or pain; or any unusual bothersome effects.

Table 4

Interactions

Concluded from page 7.

We have continued to develop the non-traditional pathway to the Pharm.D. degree. Over 260 pharmacists are currently enrolled, and we expect our first graduates by the end of this year. The originality of this program is widely recognized throughout the country. In addition, demand for the Non-traditional Pathway to the Pharm.D. grows as shown by the fact that the quality as well as number of applicants is increasing. We expect to see the first group of students to graduate within the year.

Leading

The progress of the School depends upon the leadership of individuals.

The faculty, alumni, and students are not only leaders in Maryland, but also nationally. George Dukes will be installed as President-Elect of the American College of Clinical Pharmacy, Rebecca Finley is President of the American Society of Health-System Pharmacists, and Frank Palumbo has just completed a term as President of the American Pharmaceutical Association. Two of our alumni are also leading national organizations: Calvin Knowlton is President of the American Pharmaceutical Association and Brian Kahan is President-Elect of the American Society of Consultant Pharmacists.

We take pride in the accomplishments to date. We recognize, however, the challenges still ahead. We continue to require the support and assistance of MPhA and its members as we face these challenges.

MP

Continuing Education Quiz

August 1995 -- Antiallergy Agents

This month's questions are taken from the article on the new antiallergy agents that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. There is **no charge** for this quiz for MPhA members (non-members \$5.00). The completed quiz for this issue must be received by January 31, 1996. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly. **ACPE # 186-144-95-027-H01**

Name _____

Address _____

City/State/ZIP Code _____

1. Acrivastine is a(n):
 - a. antihistamine
 - b. corticosteroid
 - c. decongestant
 - d. mast cell stabilizer
2. When used in connection with allergic rhinitis, the term "perennial" refers to symptoms that:
 - a. occur during the seasonal periods when pollen count is high.
 - b. occur at any time of year.
3. Conjunctivitis refers to an excess of blood in the:
 - a. white portion of the eye
 - b. crystalline lens
 - c. membranes lining the eyelid
 - d. hair follicles in the eyelid
4. Levocabastine is a(n):
 - a. antihistamine
 - b. corticosteroid
 - c. decongestant
 - d. mast cell stabilizer
5. The current theory for the mechanism of action of Flonase and Rhinocort is that they inhibit the release of all of the following mediators *except*:
 - a. cytokines
 - b. histamines
 - c. leukotrienes
 - d. serotonin
6. All of the following are appropriate in counseling patients receiving Livostin *except*:
 - a. shake the container well before using.
 - b. do not touch the applicator to any surface.
 - c. apply to one nostril and then the other.
7. Which of the following is true about Flonase and Rhinocort?
 - a. They both come in pressurized metal containers.
 - b. They are both indicated for treating asthma.
 - c. Patients should gently blow their nose before using either product.
 - d. They both contain the same active ingredient.
8. Lodoxamide is a(n):
 - a. antihistamine
 - b. corticosteroid
 - c. decongestant
 - d. mast cell stabilizer
9. Rhinorrhea refers to increased secretion of fluid from the:
 - a. ears
 - b. mouth
 - c. eyes
 - d. nose
10. As part of the inflammatory response, mast cells attack which of the following types of antibodies?
 - a. IgA
 - b. IgC
 - c. IgE
 - d. IgG

CLASSIFIED ADS

Services

20% DISCOUNT on awards, plaques, trophies, and engraving to MPhA members. Call Rudy Winternitz, P.D. at Washington Trophy Center, (202) 966-1255.

BILLING PROBLEMS? We are "the" experts in problem reimbursement. We have over a dozen years experience in the pharmacy billing field, and seven in the infusion/home care industry. Even if you think your practice is going well, let us give you an estimate of how we can increase your reimbursement. Call now for a prompt, professional and personal billing service. Call (410) 282-0285.

PHARMACISTS: prn PLACEMENT AGENCY for temporary and permanent placement. Fine out why more and more pharmacies are turning to PHARMACISTS: prn to fill all of their pharmacy staffing needs. Only 10% permanent placement fee, with 60 day guarantee. Temporary staffing services also available. Competitive prices. Rates for temps include all payroll taxes, FICA, workers' comp, liability insurance, etc. Almost a decade in providing pharmacy personnel services in every practice setting. Call PHARMACISTS: prn at (800) 832-5560.

THINKING ABOUT MOVING to South Florida? Retiring or looking for a winter home. Now is the time to buy. Let me put you in your dream home. Maryland pharmacist now Florida realtor, affiliated with one of the top independent real estate firms. Let us do the looking for you. Call Gary Taylor, Contemporary Realty (800) 635-4486. Home: (407) 369-1393, FAX: (407) 790-9249.

WHAT DO STEAMED CRABS, the Orioles and *PharmaSTAT* have in common? They're all superior local products that cannot be duplicated outside of Maryland. *PharmaSTAT* is a Maryland company that has been providing quality pharmacists to Maryland pharmacies for 9 years. We have the largest active pool of pharmacist in the state, and have a proven track record. FT & PT pharmacists are available. Guaranteed lowest rates in the state! Need a pharmacist? Call *PharmaSTAT* at (410) 659-STAT.

PHARMACISTS REHABILITATION COMMITTEE For private, confidential referrals call (410) 727-0746 or (410) 706-7513.

Rx LICENSE TAGS are still available! A special benefit "for members only" that costs only a nominal fee. If interested, call Mary Ann at the MPhA offices toll-free, (800) 833-7587.

Positions

PHARMACISTS Join Maryland's oldest and largest pharmacist agency -- *PharmaSTAT*! FT & PT opportunities are available now. Enjoy flexibility, excellent pay rates, benefits and cash bonuses. We offer jobs, not empty promises. Join *PharmaSTAT*! For information call (410) 659-STAT.

PHARMACIST AVAILABLE Bethesda pharmacist available for occasional relief. Weekends or evenings after 6. Strong counseling skills. Prefer independent. Willing to travel on weekends. Call (301) 215-6775.

LICENSED PHARMACISTS Full- and part-time positions available in various Baltimore locations. Management background a plus. Positions may lead to various management career paths. Benefits include: medical package, flexible spending accounts for non-covered health and dependent care expenses, term life and accidental death and dismemberment coverage, 401(K) plan, CE programs. Send resume to: Giant Discount Drug, Dept 541, PO Box 1804, Washington DC 20013 or call (301) 341-8700, ext. 1428. EOE.

PHARMACY JOB OPPORTUNITIES Full and part-time, permanent and temporary, competitive pay and excellent benefits (accrued vacation pay, direct deposit, bonus plans, liability insurance, temporary health package, 401(k) plan, etc.) Positions in all practice settings. For more information, call PHARMACISTS:prn at (800) 832-5560.

PHARMACIST WANTED Evening (5-8 pm) pharmacist needed. Must have strong counseling skills and enjoy compounding. Name your hours - days - and pay rate (within reason). Call (410) 757-3522. Cape Drugs, Cape St. Claire Road, near Annapolis.

Have something to sell, rent, or trade? Need a pharmacist? Looking for a new position? MPhA members can place a classified ad in *The Maryland Pharmacist* for free. MPhA will remove member ads after six months unless otherwise notified by the member. Non-members may also place a classified ad. The ad placement charge is \$10 for a maximum of 50 words plus 50 cents per word greater than 50. To place an ad, call MPhA at (800) 833-7587.

Rentals

OCEANFRONT OC CONDO Fully furnished, 2 BR, 2 BA, cable TV, VCR, W/D, indoor pool, lighted tennis courts, sauna, gameroom. Convenient location, Seawatch at 115th Street. Great off season rates, call now for more information, (410) 647-6924.

Important Numbers

MPhA Offices

(410) 727-0746
(800) 833-7587 toll-free in Maryland
(410) 727-2253 FAX

Mid-Atlantic DUR, Inc.

(410) 727-6122
(800) 833-7587 toll-free in Maryland

MSHP Offices

720 Light Street
Baltimore, Maryland 21202
(410) 752-3318
(410) 752-8295 FAX

Maryland State Board of Pharmacy

4201 Patterson Avenue
Baltimore, Maryland 21215
(410) 764-4755
(800) 735-2258

Maryland Division of Drug Control

4201 Patterson Avenue
Baltimore, Maryland 21215
(410) 764-2890

American Pharmaceutical Association

2215 Constitution Avenue
Washington, DC 20037
(202) 628-4410

N-A-R-D

205 Daingerfield Road
Alexandria, Virginia 22314
(703) 683-8200
(800) 544-7447 toll-free



What's Maryland pharmacy's best kept secret to successful personnel placement?

PHARMASTAT!

Secret #1

PHARMASTAT guarantees that they have the lowest rates in the state! If you ever find a lower rate, they'll beat it by \$1 per hour

Secret #2

PHARMASTAT has no cancellation penalties. Other placement agencies charge you for canceling, no matter what the advance notice or circumstances. *PHARMASTAT* doesn't!

Secret #3

PHARMASTAT doesn't have multi-page confusing contracts. Their contract is a simple one page document. And, signing up with *PHARMASTAT* doesn't require you to use their services.

Secret #4

Local ownership. *PHARMASTAT* knows the area. *PHARMASTAT* knows the people. *PHARMASTAT* pharmacists are computer matched to the special needs of your pharmacy!

Secret #5

PHARMASTAT has been serving Maryland for 9 years. They have more than 200 pharmacists available now! With the largest pool of high quality pharmacy personnel in the Mid-Atlantic area, how could you go wrong?

The secret's out! And it's simple!

Need a Pharmacist?

Call *PHARMASTAT*

(410) 659-STAT

NEWSLETTER

The Maryland Pharmacists Association

650 Lombard Street

Baltimore, Maryland 21201

(410) 727-0746

Call for Nominations

The Nominating Committee of the Maryland Pharmacists Association is seeking pharmacists who are interested in serving on the Maryland State Board of Pharmacy. Two pharmacist positions, currently occupied by Drs. Melvin Rubin and Robert Kabik, will be available.

The appointment process allows for any pharmacist in Maryland to be nominated for these positions. Any citizen of Maryland, whether a member of MPhA or not, whether a pharmacist or not, may make the actual nomination. To assure balanced practice representation on the Board, MPhA's Nominating Committee will review each nomination and select candidates qualified in the following two practice settings:

Community Chain and Institutional.

To nominate a pharmacist for the Maryland State Board of Pharmacy, call the MPhA offices at (800) 833-7587 to request an official nomination form. This form must be completed and returned with the required documentation by **November 1, 1995**. No nominations submitted after this date will be considered.

Welcome New Members

A special "hello" to 13 new MPhA members:

| | |
|-------------------------|------------------|
| Rochelle Dallago-Buller | Durand Hedin |
| Johnny Moffett | Brenda Salvatore |
| William Shaughnessy | John Donnelly |
| Teri Shively | Warren Zerwitz |
| Francis Greene | Steve Neal |
| Laura Pincock | William Zappa |
| Dana Corn | |

September 1995

The MPhA Newsletter is published monthly except during the months of July and August when the issues are combined. For information about any article contained herein, contact MPhA at (410) 727-0746 or toll-free at (800) 833-7587. President: James Tristani, P.D.; Chairman, Board of Trustees: Arnold Davidov, P.D.; Production Manager: David Miller, P.D..

Number Nine, Number Nine....

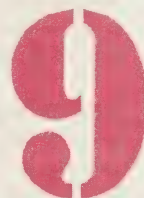
As previously reported in the MPhA Newsletter, Maryland Medical Assistance is implementing a new Medicaid Management Information System (MMIS-II). Originally scheduled for an October 1 implementation date, Medical Assistance announced in late August that the system would not be up and running until early December.

While much of the MMIS-II system will be invisible to Medicaid pharmacy providers, two major changes will require direct action by pharmacists. The first is that the Medicaid pharmacy provider number assigned to each pharmacy has been expanded from five characters to nine (by now, all pharmacy providers should have received their new number). The second change is that prescriber identification numbers have also been expanded to nine digits. Beginning December 3, 1995, all Maryland Medicaid pharmacy providers must use the nine digit prescriber identification number in order to receive on-line claims acceptance and adjudication through First Health Services.

The nine-digit numbers will be available to pharmacists in several ways. Currently, MPhA is working with Medicaid to provide a complete prescriber file on diskette or magnetic tape to chain headquarters and pharmacy software vendors. Also, MPhA will also be making a hard-copy printout available to pharmacists in mid-October. "It's clear that pharmacists need as much advance notice as possible so that we can be ready for the December deadline," said MPhA President **Jim Tristani**. "That means we have to have as much access to the revised database as soon as possible."

MPhA is also working with the Medical Assistance Policy Division to revise the composition of the Medicaid/Pharmacy Liaison Committee. Meeting quarterly, this Committee is both a structured and open forum for discussing regulations, changes, and problems within Medicaid's prescription benefit program. The next meeting is scheduled for Tuesday, October 17 at Medicaid's headquarters in Baltimore. If you're interested in participating on the Medicaid/Pharmacy Liaison Committee, please contact the MPhA offices at (800) 833-7587.

Discussion of a pharmacy "carve out" in the upcoming HCFA 1115 waiver application have continued throughout the summer with Medicaid officials by MPhA and representatives from EPIC and the Maryland Association of Chain Drug Stores. MPhA created and distributed more than 250 copies of an eight-page policy paper arguing for special consideration for the prescription benefit if Maryland continues to pursue a complete enrollment of Medicaid recipients into HMOs and other managed care delivery systems. The Administration has not made a formal decision at this point.



EPIC Network forms Alliance

EPIC Pharmacy Network, which represents about 260 independent pharmacies in Maryland, Washington, DC, and Delaware, has announced a new alliance with Richmond Medication Consultants and the Schools of Pharmacy at the University of Maryland and Virginia Commonwealth University.

Called the Alliance for Advancement of Pharmacy Care, the group is designed to form a network of pharmacies offering specialized services to the healthcare community. Participating pharmacies will be required to complete extensive training in pharmaceutical care principles and disease state management. Success of the Alliance will be fostered in several ways -- pharmacy networks will be able to market pharmacy care services to meet the changing needs of the health care community while containing costs and improving patient outcomes.

Sampling Alternative

Responding to outcries from pharmacists that sampling has outlasted its usefulness, Healthcare Delivery Systems (HDS) has announced a new program called Trial Script.

Trial Script allows pharmacist to dispense free prescription starter supplies to patients, reinforcing the pharmacists' reputation as valuable professionals who are an integral component of the healthcare team. Trial Script was designed to be easy for pharmacists to administer. Similar to a third-party reimbursement program using electronic claim submission, pharmacists simply key in the numbers provided on the Trial Script identifier and process the claim electronically.

HDS' Trial Script program is perfectly in-line with the Maryland Pharmacists Association's position on drug sampling. Your Association's established policy says:

MPhA supports the elimination of all drug sampling and its replacement with a coupon issued by the manufacturer for a starter dose that would be dispensed by the pharmacist in the same manner as any physician's prescription.

The manufacturer offering the coupon would reimburse the pharmacist for the product dispensed, plus the pharmacist's dispensing fee.

Two major manufacturers, Eli Lilly and CibaGeneva have already signed on with the Trial Script program and more are expected. For more information, call HDS at (602) 314-7000.

Major CE Events

Get out your schedules and mark down these dates! Three important continuing education programs for pharmacists are coming soon.

The Baltimore Metropolitan Pharmacists Association, in conjunction with the Maryland AIDs Drug Assistance Program and Bristol-Myers Squibb, are hosting a *free* seminar entitled **Update in HIV Therapy - 1995** on Sunday, October 29, 1995 at the Stouffers Inner Harbor Hotel from 8:00 am to 2:00 pm. The four credit program will include discussions of current HIV and AIDS management philosophies, drug interactions, and nutrition of the immunocompromised patient. Lunch is included in the program. Brochures will be mailed to both BMPA and MPhA members in September.

An in-depth review of cardiovascular disease, with a special focus on congestive heart failure and hyperlipidemia, is the subject for MPhA's **Concepts in Cardiology** seminar on Sunday, December 3, 1995. This three credit program will be held at the Marriott Hotel - BWI from 8:00 am to 12:00 noon.

Brochures will be mailed to all MPhA members in mid-October.

Last but not least, the 1996 MPhA Mid-Year Meeting will be held on Sunday, February 25 at the Loews Annapolis Hotel. In addition to our ever popular review of new drugs, we will feature two speakers on the future of healthcare and the impact of managed care on pharmacy benefit design and delivery.

Pricing Suit Postponed

In Chicago, the federal court hearing the alleged price-fixing cases against manufacturers and wholesalers has postponed the trial date from February to April 1, 1996. The two month delay is not considered significant because of the extensive amount of discovery and brief development that must be completed prior to the start of the case.

A Template for Tomorrow



**The APhA Mid-Year Meeting
February 25, 1996**

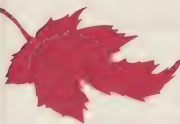


The Baltimore Metropolitan
Pharmacists Association
Cordially Invites You to Attend



A Change of Season

Our 79th Annual Banquet and Dinner Dance



Saturday, October 28, 1995
Sheraton Baltimore North Hotel
Towson, Maryland

Reception 6:30 pm

Dinner 8:30 pm

Black Tie Optional

Come celebrate the beginning of a new Association year at the premiere social event of the Maryland pharmacy community! Enjoy a lavish cocktail reception, a sumptuous dinner and then spend the rest of the evening dancing to the music of Lasting Impressions.

This year, the Baltimore Metropolitan Pharmacists Association has again selected the Sheraton Baltimore North Hotel for the site of the Banquet. Conveniently located in Towson, the Sheraton also has a special weekend discount rate available to Banquet attendees.


Seats for the 79th Banquet and Dinner Dance are only \$50 per member or member's guest. (Non-member cost is \$75). Reserve your seats by October 15, by returning the request below or by calling (410) 727-0746.

Yes! Please reserve _____ banquet seats at \$50 per member or member's guest for the 79th BMDA Banquet and Dinner Dance on Saturday, October 28, 1995.

Name _____

Address _____

Phone _____



License Renewals

The Board of Pharmacy reminds MPhA members that pharmacist license renewals were sent out by the Board in July. All renewals must be received by them no later than September 30. It is the individual pharmacist's responsibility to make sure that they have received a renewal application, completed and forwarded it to the Board of Pharmacy, and receive the new license back.

Last year, many pharmacists called the Board in late September panicking that they had been told by employers that they could not work October 1 unless they could produce a renewed license. In most of these cases, the pharmacist had waited until the middle or end of September to mail their renewal application. Since the Board process 3,500 renewals annually, pharmacists should allow at least a few weeks turn-around upon application.

With the publicity brought on by a non-licensed pharmacist error in a hospital early this year, expect institutions and chains, and many independents also, to want to see renewed licenses by October 1. Applications received after September 1 may well be delayed.

Always Double Check

Look-alike and sound-alike drug names can be misread or misinterpreted by a nurse reading doctors' orders or by a pharmacist dispensing physicians' prescriptions. Such misunderstandings can result in the administration of a drug not intended by the prescriber. Awareness of such look-alike and sound-alike drug names can reduce potential errors.

| | <u>Tinactin</u> | <u>Taractan</u> |
|---------------|-----------------|--------------------|
| Category: | Antifungal | Antipsychotic |
| Manufacturer: | Schering | Roche |
| Generic Name: | Tolnaftate | Chlorprothixene |
| Dosage Form: | Powder, Spray | Tablets, Injection |

| | <u>Isordil</u> | <u>Isuprel</u> |
|---------------|----------------|--------------------|
| Category: | Antianginal | Bronchodilator |
| Manufacturer: | Wyeth-Ayerst | Winthrop |
| Generic Name: | Isosorbide | Isoproterenol |
| Dosage Forms: | Tablets | Aerosol, Injection |

Contributed by Benjamin Teplitzky, R.Ph.

APhA Elections

Members of the American Pharmaceutical Association should have received their 1995 *Voter's Guides* by now. The *Guides* include ballots for APhA officer and trustee positions as well as the two Academies. Deadline for APhA ballots is October 13.

Self-Help Group Formed

A "Pharmacists Anonymous" group based on the 12 steps and traditions of Alcoholics Anonymous has been formed in Montgomery County. The meetings are held each Wednesday evening from 7:30 to 8:30 pm in a private home. This is intended to be a voluntary self-help group for pharmacists in recovery from or affected by the consequences of chemical dependency.

For more information, call Toni P. at (202) 994-1750 during working hours and at (301) 977-8884 during evenings for information and directions.

Upcoming Health Events

Telephone numbers are provided for additional information and promotional materials.

October

| | |
|-------------------------------|----------------|
| Breast Cancer Awareness Month | (212) 382-2169 |
| Lupus Awareness Month | (800) 558-0121 |
| Liver Awareness Month | (201) 256-2550 |
| SIDS Awareness Month | (800) 221-7437 |
| Talk About Rx Month | (202) 347-6711 |
| Pharmacy Week, 10/22-28 | (800) 237-2742 |

November

| | |
|---------------------------|----------------|
| Alzheimer's Disease Month | (312) 335-8700 |
| Diabetes Month | (703) 549-1500 |
| Epilepsy Month | (301) 459-3700 |
| Hospice Month | (202) 546-4759 |

AIDS Information FAST

The AIDS Clinical Trials Information Service is a central resource providing current information on federally and privately sponsored clinical trials for AIDS patients and others infected with HIV. This service is a Public Health Service project provided collaboratively by the FDA, CDC, and others. Maryland pharmacist **Steve Wickizer** was instrumental in establishing this program.



Physicians, pharmacists, individuals with HIV and their families and friends, can find out more about AIDS clinical trials by calling the Service's toll-free number. All calls are completely confidential. Bilingual health specialists are available for Spanish-speaking callers. Call AIDS Clinical Trials Information Service Monday through Friday, 9:00 am to 7:00 pm EST at (800) 874-2572.

Counterfeit Shampoo

Procter & Gamble is waging a major battle against a distributor who has sold contaminated and falsely labeled Head & Shoulders shampoo. The counterfeits are easy to spot. The bottles are long-necked and lack a triangular recycling symbol on the bottom.

Post Scripts

- R Zeneca Pharmaceuticals and Bayer have signed a letter of agreement for Zeneca to market a new calcium channel blocker in the US. Under the agreement, Zeneca will have exclusive rights to sell nisoldipine (Sular) extended release tablets. The product is expected to reach pharmacy shelves in early 1996.
- R CibaGeneva has received FDA clearance to market Lotrel, a amlodipine/benazepril combination product for hypertension. Of the 50 million Americans with hypertension, almost 50% are prescribed either a calcium channel blocker or an ACE inhibitor. CibaGeneva plans to capitalize on treatment failure with this unique combination.
- R Univasc (moexipril HCL) is a new once-daily ACE inhibitor offered by Schwarz Pharma. Distinguishing itself from other ACE manufacturers, Schwarz has price Univasc 20% less than the lowest brand-name ACE inhibitor currently available.
- R A recent FDA letter to State Boards of Pharmacy reminds pharmacists that Oramorph SR (morphine sulfate sustained release tablets by Roxane) are *not* considered therapeutically bioequivalent to MS Contin (morphine sulfate controlled release tablets by Purdue Frederick). They are classified in FDA's Orange Book as Category "B" products. For Maryland pharmacists, that means either a new prescription or prescriber authorization to substitute one for the other prior to dispensing.
- R A related substitution concern surrounds CibaVision's Betimol (timolol ophthalmic solution) and Merck's Timoptic (timolol maleate ophthalmic solution). While the two products contain the same ingredient, they are *not* AB rated, are *not* generically equivalent, and therefore cannot be substituted.
- R Following reports of serious reactions and some deaths associated with concomitant use of the antidepressant Zoloft (sertraline) and monoamine oxidase inhibitors, Pfizer has revised Zoloft labeling to state that the use of the drug is now contraindicated -- not just discouraged -- in patients receiving MAOIs.
- R This month, Mead Johnson will launch Boost, its first mass-market consumer product. Boost is a low-fat, nutritional energy drink made for healthy active adults who want to eat right but don't always have the time. The product is a nutritionally complete, lactose-free, milk based beverage sold in four packs of 8 ounce single-serving cans.

- R Swept along in the growing move of prescription products to OTC status is Children's Motrin Suspension. The OTC Children's Motrin (ibuprofen suspension) strength is 100mg/5mls and is for children between the ages of 2 to 11 years.
- R Cardinal Health, a major wholesaler, announced plans to purchase Medicine Shoppe International. Under the terms of the agreement, the Medicine Shoppe franchise will be a wholly owned Cardinal Health subsidiary. The purchase price? Approximately \$348 million!
- R Ooops! In announcing the University of Maryland School of Pharmacy Alumni Association's 1996 officers we forgot to mention that **Neil Leikach** is their new Treasurer.
- R 1995 Maryland grad **Vanessa Kluth** and Howard grad **James Kennel** were honored with the Patient Care Award from SmithKline Beecham. The program recognizes pharmacy students who demonstrate exceptional abilities in patient communication, counseling, case presentation, and drug therapy monitoring.
- R A recent onslaught of direct-mail brochures to Federal Employees touting the benefits of mail-order drug delivery has raised a number of questions about the program. The Federal Employees drug benefit permits the use of mail-order however it is only an option. Federal workers are not required to use the program. Pharmacists who have a large population of Federal workers and family members may wish to step-up their counseling and communication about the benefits of local pharmacist contact.

Just for Students

The

Interorganizational Council on Student Affairs, a coalition of national and state pharmacy organizations, has issued



its annual *IFEID* booklet. Popularly dubbed the "If I'd only known" guide, *IFEID* lists scholarships, loans, grants, residencies, awards, internships and research experiences available to pharmacy students. The guide includes complete contact information for students to use in applying for the many financial aid opportunities.

MPhA student members may obtain a free copy of the *IFEID* booklet by calling the offices at (800) 833-7587 or stopping by the Kelly Building on campus. MPhA Executive Director **David Miller** represents the 50 state pharmacy associations on the Interorganizational Council on Student Affairs.



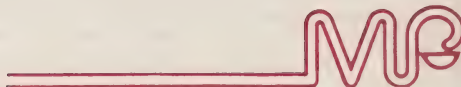
Maryland Pharmacy Event Calendar

- Sept 18-23 NARD OTC Health Support and Appliance Fitting School and Examination, Dallas, TX. Call (800) 544-7447.
- Sept 21 **MPhA Board of Trustees Meeting, 7:00 pm, MPhA offices.**
- Oct 8-11 NARD Annual Convention, Las Vegas, NV. Call (800) 544-7447.
- Oct 17 Medicaid/Pharmacy Liaison Committee, 10:00 am, Medicaid Offices. Call (410) 225-1455.
- Oct 20-21 MSHP Annual Seminar, Sheraton Society Hill Hotel, Philadelphia, PA.
- Oct 20-22 APhA-Academy of Students of Pharmacy Regional Meeting, Baltimore. Call (800) 237-APhA.
- Oct 23-28 NARD Support and Appliance School and Exam, Fort Mitchell, KY. Call (800) 544-7447.
- Oct 28 BMPA Annual Dinner Dance and Awards Banquet, Sheraton Towson. See enclosed flyer.
- Oct 29 Update in HIV Therapy, BMPA CE Program, Stouffers Inner Harbor. Call (800) 833-7587.
- Nov 1 Care of the Asthmatic Patient, CE Program, GBMC Conference Center. Call (410) 828-3670.
- Dec 3 Cardiology Concepts, MPhA CE Program, BWI Marriott Hotel. Call (800) 833-7587.**
- Dec 13-17 ACA Specialty Training Program in Respiratory Diseases. Call (703) 684-8603.
- 1996
- Jan 15-20 NARD Health Support and Appliance School and Exam, Orlando, FL. Call (800) 544-7447.
- Feb 25 **MPhA Mid-Year Meeting, Loews Annapolis Hotel, Annapolis, Maryland. Call (800) 833-7587.**
- March 10 AZO Fritz Berman Memorial Seminar, "Diseases of the Eye." Details to follow.
- June 16-19 114th Annual MPhA Convention, *Charting a New Course*, Sheraton Ocean City Resort.**

NEWSLETTER

The Maryland Pharmacists Association

650 Lombard Street
Baltimore, Maryland 21201

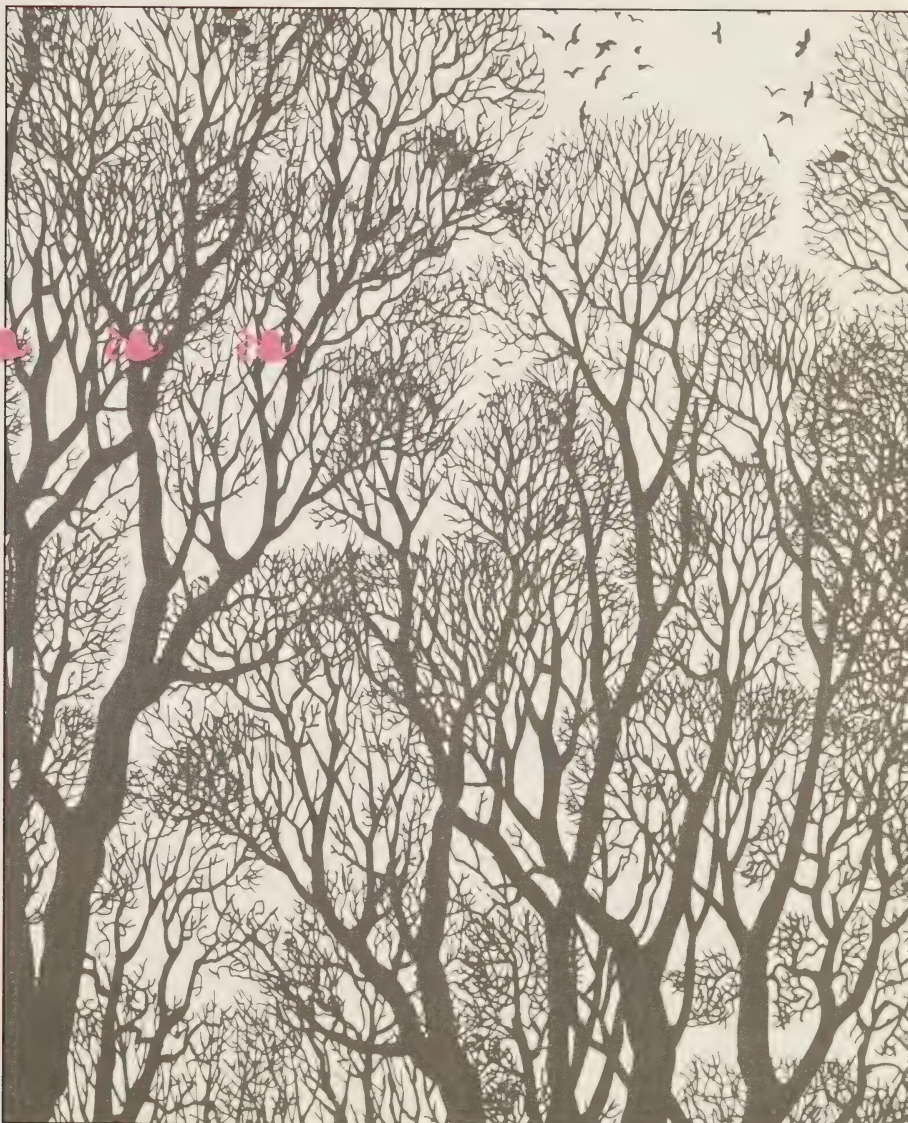


MARYLAND PHARMACIST

September, 1995

Vol. 71, No. 9

- \$64 Question
- Rehab Support
- To Compound or Not to Compound
- UR Confidential
- Interactions
- CE: Alzheimer's Disease



If you're a Valu-Rite member,
here's another way to
boost your profits.



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a Valu-Rite member,
maybe you should be.



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MARYLAND PHARMACIST

The Official Publication of The Maryland Pharmacists Association

September 1995

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President's Commentary

Decisions, Decisions

As you read this article, decisions being made that are going to effect you and the profession for the next 50 years. Under way is a process that will greatly alter the daily routine of every Maryland pharmacists.

The biggest decision is to review, update, and rewrite the Maryland Pharmacy Practice Act. The reason for this decision is simple. Pharmacy has evolved into areas that the current Practice Act never anticipated. In fact, if you actually read Title 12 of the Health Occupations Article (our section of the Maryland laws) you'll be surprised to see how many restrictions, laws, regulations, disciplinary actions, etc., center around things we do with drug products. Except for the section on mandatory patient counseling for Medical Assistance recipients -- a section that was required by Congress -- there isn't anything that deals with the pharmacists rights and responsibilities to care for *patients*.

Whose decision is this? Thanks to some progressive thinking of the Maryland State Board of Pharmacy, a Task Force to revise our Practice Act was formed in mid-August. This multi-specialty group has been charged with looking at other state's laws and regulations, reviewing our own, and projecting what kind of professional oversight will be need next year, five years, and ten years from now. In addition to the Board's efforts, MPPhA's Pharmaceutical Care Committee began reviewing the Practice Act last spring so that our organization could identify the Act's deficiencies and limitations on what a pharmacist can or cannot do.

Historically, the Maryland Board has done what I believe to be an outstanding job in protecting the public safety as well as governing the pharmacy profession. In the last several years, changes that have occurred, such as the diversification of practices, pharmaceutical care, and the continuing

evolution of pharmacists from bottle fillers to information fillers have created new and different demands on the Board.

Pharmacists around the state must become involved with this process of change. The *nuts and bolts* methodology of the Pharmacist Practice Act should have as much input as possible from the different specialties within pharmacy. Keep in mind that as pharmacy moves towards a role of providing and monitoring drug therapy, what's right and what's wrong becomes very subjective. It's easy for the Board of Pharmacy inspectors to identify a misdispensed medication or a refrigerator that isn't exactly the right temperature. It's much more difficult to identify an ineffective counselor or a pharmacist who fails to address a compliance issue.



James Tristani, P.D.
1995-96 MPPhA President

I hope the overwhelming majority of Maryland pharmacists are not just going to complain about the state of the pharmacy profession. I hope instead that they will take the time to investigate the proposed changes **before** they become reality. To that end, I will

ensure that MPPhA prints the draft changes to the Practice Act in this and other publications to maximize exposure and to assure that as many pharmacists as possible are kept informed and involved.

You, however, must read and react! You must provide us and the Board with input. You have to care enough about the profession that puts money into your pocket on a regular basis to pay attention to what's occurring with the Practice Act Revisions. Otherwise, one of those decisions made without your input just might be to eliminate pharmacists altogether.

MP

The \$64 Dollar Question

David Miller, P.D., Executive Director
Maryland Pharmacists Association

containment strategies, and oversight of the health care payment system including annual adjustment goals.

The Commission started with a \$5 million annual budget funded by insurers and providers. The provider community is responsible for paying 1/3 of the \$5 million through an additional fee attached to every professional license issued by the Department of Health and Mental Hygiene.

The Commission

In 1993, the Maryland General Assembly passed sweeping legislation to reform Maryland's health care system. Outrage at skyrocketing insurance premiums and concern over the inability to provide reasonable priced health insurance was the prime reason for the legislature's action. House Bill 1359 (HB 1359) coordinated all of Maryland's health reform initiatives under a single governmental agency... the Health Care Access and Cost Commission.

This Commission is composed of seven individuals appointed by the Governor, four of whom may not have any connection with the management or policy of a health care provider or payor. HCACC is an independent agency with wide ranging powers as well as general authority over the implementation of HB 1359. They are charged with several major tasks: development of a comprehensive standard benefit package, establishment of a medical care data base, creation of cost

Standard Benefits Package

The HCACC is charged with developing a Comprehensive Standards Benefit Plan (Plan). This plan must be the *minimum* coverage offered by all Maryland insurance carriers to the small employer group market. As with other insurance reform provisions contained in House Bill 1359, this plan may expand into the general insurance market for large employers. Because of MPhA's efforts, prescription drug coverage with a \$150 annual deductible is part of the standard benefits plan enacted by the Health Care Access and Cost Commission in 1994.



Pharmacists whose Maryland licenses end in an odd number were in for a pleasant surprise last month when they received their biennial renewal forms from the State Board of Pharmacy.

Sure enough, in an age where everything costs more than it used to, the Maryland Board of Pharmacy actually *reduced* the license renewal fee from the previous \$130 to \$95.

However, shock quickly followed that surprise. Tucked at the bottom of the form was the first \$64 per license "user fee" assessment from the Health Care Access and Cost Commission (HCACC).

What is that \$64 for? Who is the Health Care Access and Cost Commission? And how come pharmacists have to pay it?

What's going on here?

The maximum annual premium, averaged across a carrier's community rating population, for this basic plan may not exceed 12% of the annual average wage in Maryland. The HCACC can adjust the Plan annually to meet the 12% ceiling by changes in benefits, deductibles or co-pays. There may be separate plans for HMO's and indemnity plans.

Any health benefits offered in addition to the standard benefit plan, must be offered and priced separately by carriers. The effect of the standard benefit plan is that all carriers in the small group market will offer the same benefits, deductibles and co-pays, and thus facilitate cost comparisons and the need for the carriers to compete on an equal footing.

The result of the standard benefit plan has been positive. Small employers who were previously unable to obtain insurance coverage at reasonable premiums can now shop for, compare, and more importantly, afford health insurance for their employees. As reported in last month's *MPhA Newsletter*, the Maryland Insurance Commission has a series of brochures available to the public that lists each Maryland insurance company, HMO and PPO prices for the standard benefit plan.

Medical Care Data Base

The HCACC is also charged with developing a medical care database. This database -- consisting of information on health services rendered by all health care practitioners -- will be used by HCACC to develop cost containment strategies. The data is intended to allow consumers, employers and insurers to comparison shop for health

services rendered by all health care practitioners.

HCACC must adopt regulations to ensure the confidentiality of physician-patient privilege. HCACC will analyze this data and annually publish the total reimbursement for all health care services, the annual rate of change, variations in fees and utilizations on a statewide basis and by health service areas. The data base, once fully developed, should greatly assist in the control of health care costs. Another source of data will be developed to provide comparative evaluation of HMO's to insurance indemnity plans based on costs as well as quality.

Pharmacy will be one of the provider groups that must supply data to the HCACC. MPhA has reviewed and commented on HCACC'S proposed data collection regulations. While the original plan was to obtain the data directly from providers, HCACC has instead chosen to require that the data be supplied by claims processors thereby eliminating excessive provider administrative burdens. Due to the large number of providers who must supply data (an estimated 60,000), it is likely that pharmacy will be one of the later providers added to the database system.

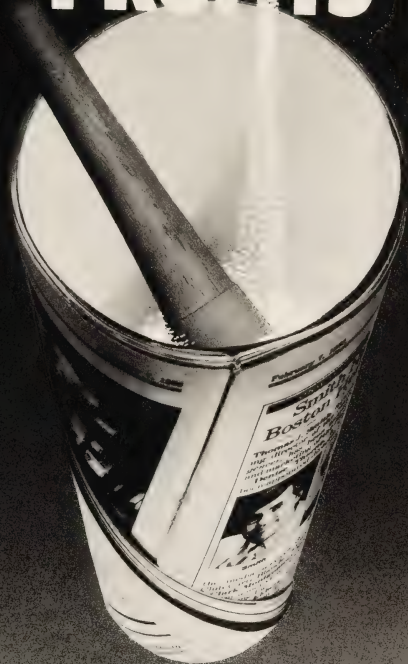


Payment System Oversight

The Health Care Access and Cost Commission is also authorized to develop a payment system for health care practitioners. This payment system provides a framework for determining the ultimate price for health care services. Except under extraordinary circumstances described below, the marketplace and not HCACC will determine the final price of a health care service.

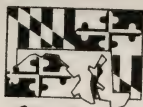
The payment system will be based on the following factors: the practitioners' resources (e.g., overhead and expertise); the value of the service (e.g. complexity); and a conversion modifier. The ultimate price for a service call will be arrived at by multiplying the numeric value of these three factors. The conversion modifier is the key to setting the dollar value of a service.

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HCACC may establish health care cost annual adjustment goals for the cost of health care services and the cost for a particular service. For example, the HCACC may set a cap on the price for a general physical. If spending exceeds these goals or caps, the HCACC through voluntary and cooperative arrangements with practitioners may make an effort to bring spending into compliance with this goal. If these efforts prove unsuccessful, HCACC may force a reduction. Thus, HCACC will set the price for health care services only under extraordinary conditions. It is unclear at this point whether HCACC will also increase compensation for a service if the existing price for that service is below the combination of the three factors.

Summary

There are many positive parts of Maryland's health reform statute that will benefit pharmacy employers. It is likely that data from pharmacy claims will form part of the Maryland health care database; when, and to what extent given the massive quantities of claims that pharmacists process, has not been determined. Practice standards and guidelines will be required by the HCACC for health professionals. Pharmacy will no doubt be included. MPhA will be strongly in favor of using those principles and guidelines previously developed by the Association and published in the January 1993 issue of *The Maryland Pharmacist*. MPhA firmly believes that the profession, and only the profession, should determine and enforce standards of practice.

What Can I Do to Help Fight the \$64 Pharmacist Assessment?

If you don't want to have to pay the \$64 HCACC assessment every two years, an assessment that may grow depending on the budget needs of the Commission, *you need to be a member of the Maryland Pharmacists Association!*

Obtaining an exemption from the HCACC fee is one of MPhA's top priorities this year. Every pharmacist will benefit from this exemption and every pharmacist has an obligation to support our efforts to obtain that exemption.

Only your professional association can represent your interests. Only your professional association can fight to keep your hard-earned money in your pocket.

But, there's still the question of that pesky \$64 assess from every pharmacist.

For the first two years of HCACC's existence, pharmacists were exempted from paying there portion of the Commission's funding. We were swept in during a revision of the statute to assure that all providers were included.

However, the Health Care Access and Cost Commission does have the ability to grant exemptions to groups of professionals. Both nursing and dentistry have already successfully petitioned to be exempted from the user fee assessment. Obtaining an exemption for pharmacists is a major priority for MPhA in the coming year.

Right now, every pharmacist who has a Maryland license -- including those that reside out-of-state, are required to pay the assessment. If you do not include the fee in your license renewal, your license will not be issued.

Rest assured that MPhA will do everything possible to save you that \$64 (and maybe more in the future).

But we can't do it without help. And that help comes in the form of dues from members. If you're not a member of MPhA, you're getting a free ride on the time, money and resources of your colleagues. Join today!

MP

At Issue

The Right Approach to the Problem of the Chemically Impaired Pharmacist

Jay Schlosberg, Pharmacy Student
UMAB School of Pharmacy

Alcohol and drug abuse is arguably one of the most complicated and destructive forces currently eroding the overall health of our society. It is estimated that less than one in ten Americans suffer from chemical dependency. Furthermore, research suggests that one in every seven to ten pharmacists may be affected by chemical dependency disease at some point in his or her career.¹ This represents an obvious problem for the health care delivery process; but it is one that can be managed. The correct approach in managing this problem must focus on reasonable treatment, rehabilitation and re-entry rather than harsh, irreversible punitive measures.

Health care providers, and especially the profession of pharmacy, should consider drug and alcohol abuse a valid disease state which can be treated or at least successfully managed. Just as with any other disease process, chemical dependency doesn't pick and choose its victims according to race, sex, age or profession. Pharmacists deserve at least the same level of understanding and treatment that others in society get when

they fall prey to substance abuse. It would be logical to assume an even higher level of understanding when considering the high stress nature of pharmacy. Treatment and rehabilitation should be the approach used in solving this problem because it is a disease and that is how diseases are managed. To amputate someone's ability to earn a living because he or she suffers from a disease is extremely counterproductive to that person's treatment.

Even though the American Medical Association "labeled" chemical addiction a medical illness in 1956, the majority of people still label it as a moral weakness, a bad habit, or a lack of willpower.² Society still makes the argument that individuals are responsible for their behavior and should be appropriately punished for such personal and professional shortcomings. This point of view is easily understood and is very useful in dealing with many of society's behavior related dilemmas. However, the uncontrolla-

ble, persistent use of drugs and alcohol present a problem too medically and psychologically complicated to solve through punishment.

Another reason for choosing treatment over termination for chemically impaired pharmacists is the price that society will pay for persecuting a valued member of its ranks. Pharmacists are generally held in high regard in terms of integrity, honesty, and reliability. There is good reason for this. Pharmacists have proven themselves academically and professionally in their communities, and this is something society should strive to preserve. If pharmacies are stripped of their licenses because of chemical dependency, they risk losing their career, source of income, community standing, home, savings, and even their freedom. Society, in turn, loses a productive tax payer who fills an important role in its health care system.

A sturdy argument against a more understanding approach to this problem is that there exists the possibility that an impaired pharmacist could do substantial harm to a patient. Being high



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or drunk on the job could result in a pharmacist delivering incomplete or negligent drug service and/or information. With this level of consequence in mind, many feel that the pharmacist, as the legal guardian of drugs, should be held to a higher ethical standard than most other professionals. That an oath and a sense of duty exists between the pharmacist, the patient, and society. That the only way to enforce the high standards of the profession is to exercise stiff punitive measures designed to punish present indiscretions and deter future ones.

It must be noted, however, that our society expands vast amounts of resources attempting to rehabilitate every type of offender from bank robber to child molester. Our society must then believe that rehabilitation can work. If members of society who have proven that they have little to offer are worthy of rehabilitation, surely the chemically dependent pharmacist is worth the same effort.

Another reasonable argument against the treatment, rehabilitation, and re-entry of chemically dependent pharmacists is that the temptation of readily available drug supplies is too great for an addict to overcome. This is certainly a very convincing point, but the truth does not support it. In fact, the incidence of recurring drug addiction among pharmacists has historically been considered to be lower than that of other health care professionals, even though pharmacists have easier access to drugs.³

Far and away the best reason to choose treatment over termination when dealing with impaired pharmacists is that many treatment programs do exist and have proven effective. A recent telephone survey found that thirty-eight states currently have Impaired Pharmacists Network (IPP) programs in operation. Current informal evidence indicates that ninety percent or more of IPP's clients successfully complete rehabilitation and reenter the profession.⁴

Programs such as IPP also have the potential to prevent mistakes made by impaired pharmacists. If pharmacists know that they are addicted to drugs or alcohol, and that the only way society deals with the problem is to revoke the legal right to practice, they will do everything in their power to hide the condition. If, however, they know that there are programs in place that will allow them to come to terms with their problem without having to face termination, many pharmacists will seek help before their impairment results in a serious mistake.

Finally, chemically dependent pharmacists who have been successfully treated, rehabilitated, and reentered into the profession can provide essential counseling and insight into a problem that represents pharmacy's number one occupational hazard. Reentered pharmacists can be useful in the rehabilitation of other substance abusing health care professionals. They could also serve as a wealth of information and advice for addicts in the general population.

Chemical dependency is a debilitating condition that affects all aspects of a person's life. The professional life of a pharmacist is a demanding and stressful one. Combination of the two results in a complicated legal, ethical, and societal dilemma which has yet to be fully resolved. As society moves to accept chemical dependency as a disease state rather than a character flaw, more reasonable solutions will prevail. The profession of pharmacy should reinforce this move by attempting to solve its own substance abuse problems through treatment rather than termination.

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Interactions

The Non-Traditional Pharm.D. Pathway

The development of the Non-Traditional Pathway to the Doctor of Pharmacy degree is an excellent example of successful interactions between practicing pharmacists and faculty at the School of Pharmacy. When the School embarked on the development of the Doctor of Pharmacy program, we were rapidly convinced by practitioners that we had an obligation to provide an opportunity for all practitioners to earn the Doctor of Pharmacy degree if they so desired. The faculty accepted that challenge and began to build a Non-traditional Pathway even as we were constructing a brand new Doctor of Pharmacy curriculum. The two projects were developed concurrently.

Unlike the process we used in developing the new curriculum, that is planning for three years before the first class was admitted, it soon became clear that practitioners in Maryland did not want to wait for a fully planned non-traditional option. They wanted to enroll in something right away! They wanted to start work immediately on a Pharm.D. program.

In response to this demand, we developed a course, *Introduction to Pharmaceutical Care*, and offered sections oriented to ambulatory practice and to institutional care. The courses were offered in the evenings at Pharmacy Hall and have been fully subscribed since the beginning. The first several times that these courses were offered, students were enrolled as *special students*, since there was no program in which to be admitted! Both students and faculty were gambling that we would end up with a program and that students would be able to transfer credits into it. Other didactic courses followed, as did the unique program of prior learning assessment designed to give pharmacists an opportunity to earn academic credit for learning acquired from professional experience.

Since no other pharmacy school had ever done prior learning assessment, Maryland's efforts were rocky. What finally emerged, however, is a model that works and is being copied elsewhere.

A year or so ago the faculty formally approved the fully-developed Non-Traditional Pharm.D. Pathway. It is integrated with the campus-based doctor of pharmacy program, leads to the same degree and uses the same curricular outcome criteria for student evaluations.

The Non-Traditional Pathway is designed for current practitioners to upgrade their practice, knowledge, and skills. It is not designed as specialty training or for career change purposes. The basic requirements to apply for admission are a Bachelor's degree in pharmacy from a U.S. accredited school of pharmacy, licensure in Maryland, and access to patients. Applicants must be actively practicing pharmacists. It is the intention of the School of Pharmacy to make this program available to as many qualified Maryland pharmacists as wish to pursue it.

Given these considerations, the problem becomes not one of a select admissions policy, but rather one of rationing available spaces over time. This is because we can only accommodate about sixty pharmacists a year in the pathway. The availability of faculty during the experience phase of

the program is limited, since it must operate concurrently with the experience training of one hundred students a year in the full-time Pharm.D. program.

Therefore, we approached the admissions process in two ways for the fall of 1995. Half of the available slots were allocated for discretionary selection by the Admissions Committee. This was based on a desire to make sure that our own employees, i.e., volunteer faculty and preceptors, obtain the training they need to improve their skills as volunteer faculty to help with our faculty resource problems. By doing this, we can more rapidly meet our total faculty needs over the next few years.



David A. Knapp, Dean
UMAB School of Pharmacy

The remaining half of the slots were filled through a lottery system that included all other qualified applicants. Since the applicant pool included pharmacists who had obtained their pharmacy degree at different times over thirty years and who bring to the program vast differences in experience, we could come up with no more logical way to allocate spaces in the program than a lottery. Given the negative feedback we have already received on the lottery approach, we are scrapping it for the Fall of 1996. A better method is being devised and will be communicated to potential applicants this fall. Once admitted, every student will have to meet the rigorous standards and ultimate outcome criteria of the same excellent Doctor of Pharmacy program. **MP**



Call for Nominations

The Nominating Committee of the Maryland Pharmacists Association is seeking pharmacists who are interested in serving on the Maryland State Board of Pharmacy. Two pharmacist positions, currently occupied by Drs. Melvin Rubin and Robert Kabik, will be available.

The appointment process allows for any pharmacist in Maryland to be nominated for these position. Any citizen of Maryland, whether a member of MPhA or not, whether a pharmacist or not, may make the actual nomination. To assure balanced practice representation on the Board, MPhA's Nominating Committee will review each nomination and select candidates qualified in the following two practice settings:

Community Chain and Institutional

To nominate a pharmacist for the Maryland State Board of Pharmacy, call the MPhA offices at (800) 833-7587 to request an official nomination form. This form must be completed and returned with the required documentation by **November 1, 1995**. No nominations submitted after this date will be considered.

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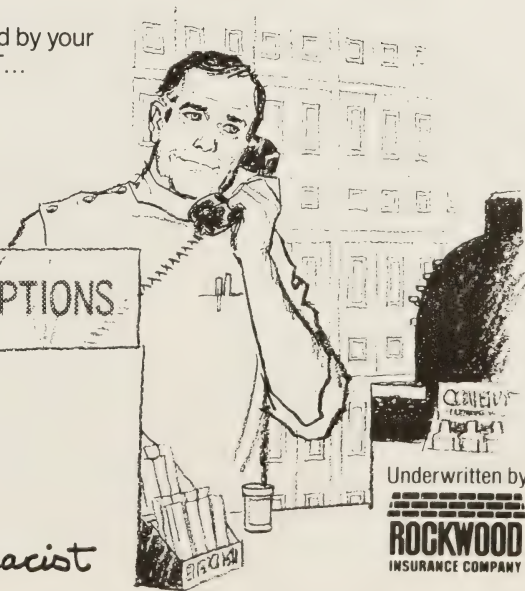
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Ten Years With the Board of Pharmacy

*Steven Cohen, P.D., President
Maryland State Board of Pharmacy*

I have recently completed a ten year term on the Board of Pharmacy. Over the years, many critical issues have come to the Board's attention. I hope most of those were handled in a competent and timely fashion and that our decisions were in the best interest of the citizens of Maryland and our profession. Some of those issues included physician dispensing, mid-level prescribers, chemical dependency, fax regulations, institutional regulations, technology assessment, the Board selection process, and a variety of clinical and administrative issues.

In the future, the Board and pharmacy will face new and different challenges. Pharmacy practice continues to change. Just look at the recent specialization of pharmacy into radio-pharmaceuticals, infusion therapy, home care, oncology practice, sub-acute care, long term care, and the further development of the pharmacists' influence on patient care directly. In addition, the pressure of operating in a managed care and managed cost environment continues to grow.

The apparent product orientation of some practitioners has always been a source of concern to me. I believe we put our careers and our profession at risk by not focusing more on how we can influence the prescribing decisions made by other practitioners. I know the evolution of pharmaceutical care will help focus more on this aspect of our abilities, but time is of the essence.

Many other healthcare practitioners are fighting for the right to do what we can do best. Technology also begins to influence the time line. As more and better technology is promulgated to diminish the "distribution" function of pharmacists, more pressure will come to bear to use fewer licensed professionals.

Hence, the need is great to demonstrate our ability and willingness to perform the clinical, as well as the traditional distribution and dispensing functions. Education of prescribers, patients, families, and other care providers is essential. Helping to manage the cost of pharmaceutical care by influencing the prescribing decision, helping to manage and monitor care and helping to provide education, is essential to our continued success.

Likewise, it is necessary for each individual pharmacist to take personal responsibility for applying the knowledge and skill that they have, and by acquiring more when they need it. Each of us must take full advantage of the opportunities that our license affords us and not be afraid to make professional decisions. We must stop deferring to others (an employer, a manager, a prescriber, etc.) for decisions that we alone are empowered to make as professionals. Too often the employee pharmacists appear before the Board and claim that they were only following someone else's decision -- the fault for problems is not their own, it belongs to -- indicates to the Board that someone other than themselves decided what to do in a particular circumstance.

Pharmacy is a profession and one of the hall marks of a profession is the power to make independent judgements. And while no one is proposing that "prescribing" be our job, we certainly are empowered to decide what intervention is necessary once initial prescribing directions are provided to us.

Monitoring initial and ongoing therapy, patient compliance, drug interactions, education, adverse effects, over the counter drugs and aspects of pharmaceutical care exist for us to show our professional expertise. Exercise the professional autonomy afforded by your license. Demonstrate to the changing healthcare world that pharmacy *and you* are up to the challenge.

MP

Pharmacists Rehabilitation Committee Receives State Support

*Tony Tommasello, B.S., M.S.
Director, Office of Substance Abuse Studies
UMAB School of Pharmacy*



On May 18, 1995, Governor Paris Glendening signed Senate Bill

329 into law. This bill permits the Maryland State Board of Pharmacy to provide funds to the Pharmacists' Rehabilitation Committee (PRC) for the purpose of supporting its activities on behalf of pharmacists in the state.

For more than ten years the PRC has been providing advocacy and support for pharmacists suffering from the disease of chemical dependence. The May 1992 issue of *The Maryland Pharmacist* (Vol 68, No. 5) offers a ten year review of the Committee's activities and covers the design and function of the program.

The decision by the state to support the PRC is a welcomed new development, but with it comes concerns about the potential for the pharmacy community to misinterpret the support from the Board as a threat to the Committee's confidential handling of cases, and the perception that no additional funding is needed by the Committee.

As SB 329 struggled through the House Environmental Affairs Committee it was subjected to an amendment which threatened the integrity of the PRC program. The amendment would have required the PRC to be subsumed under the Board of Pharmacy. This structure parallels that of the nurses' professional recovery program and, while it would have facilitated financial accountability, it could have jeopardized the reach of the program.

An analysis of the nurses' program revealed a case rate of 2.27 per 1,000 licenses, which is just about half of the case rate of 4.0 per 1,000 licenses followed by the PRC. Furthermore, when one examines the breakdown of cases followed by the PRC it turns out that half come to the Committee from sources other than board referrals. This suggests that requiring impaired practitioners to go through a licensing Board is a barrier to accessing the services of a professional recovery program.

The defeat of this amendment means that the PRC can continue to assure those who are self-referred or referred by a second party (family member, employer, etc.) that their addiction, or other cause for referral, can be addressed without exposing them to license sanction. The founding principle of the PRC is to enhance access to addiction treatment and to reduce the stigma associated with the disease of chemical dependence through confidential referrals to competent treatment providers. Thus, when a pharmacist comes to the Committee through mechanisms other than board referral the opportunity exists to enter treatment, engage in a recovery program, achieve stable sobriety, and sustain the practice of pharmacy without significant interruption.

The PRC must, however, respond to situations in which an impaired pharmacist, after having made the decision to enter the PRC program, fails to achieve sobriety and continues to practice. Under the terms of his treatment contract with the PRC the pharmacist who continues to abuse substances, and thereby places the public health at risk by practicing while impaired, is reported to the board with a recommendation for an emergency suspension of his license. Once such a report is made, the case falls under the purview of the Board and reporting obligations are activated. Despite this unfortunate turn of events the pharmacist is not abandoned by the PRC which continues to provide advocacy on his behalf in matters that relate to future actions concerning his license or in identifying employment opportunities once a track record of sobriety is established.

When the Board of Pharmacy investigates a pharmacist for violation of the Pharmacy Practice Act and finds reason to suspend or revoke his license it will refer the case to the PRC for follow-up if there is a question of drug or alcohol abuse. These Board referred pharmacists account for about half of the PRC caseload; they are directed to competent addictions specialists for diagnosis and treatment planning.

After treatment is initiated these cases carry a burden of reporting to the Board on a quarterly basis regarding the nature of the pharmacist's compliance with the PRC contract. To supply these reports the PRC must maintain a set of documents that track a pharmacist through his recovery efforts. These documents include therapist reports with results of weekly random urine testing; employer reports indicating the pharmacist's reliability and practice capability; and reports of the PRC monitor assigned to follow the pharmacist via weekly telephone contact. Reporting forms are distributed to appropriate individuals to fill out and return to the PRC program coordinator who is responsible for collecting and organizing these reports.

The obligation to make regular compliance reports in cases of Board referred pharmacists had placed an unfunded mandate on the PRC. In essence, voluntary contributions had been supporting state activities. The Committee's failure to make reports on a timely basis would ultimately jeopardize not only the Board's trust in the program but also the ability of the recovering pharmacist to regain his license at a future date. Therefore, for

purposes of both treatment enhancement and reporting requirements the PRC, an otherwise totally volunteer committee, pays for the services of a part-time program coordinator. Funding by the Board of Pharmacy assures the continued support of the program coordinator and the ongoing efforts needed to fulfill the reporting requirements associated with Board referred cases.

The total budget of the PRC must encompass services expended on behalf of all pharmacists, not just those who are Board

referred. These items include, but are not limited to: allocating funds for an initial assessment and treatment planning diagnostic interview; maintaining records of recovery on non-Board referred cases; attendance at continuing education program by Committee members to maintain addictions intervention proficiency; general office maintenance; and a portion of the coordinator's salary.



PRC President Tony Tommasello with Governor Glendening at the signing of Senate Bill 329.

Just as it was improper for the PRC to be expected to provide unfunded services on cases referred by the Board, it is equally unfair to expect the state, through the Board, to pay for services provided to pharmacists who are not under its purview. While an argument could be made that the state has an interest in maintaining a healthy pharmacy workforce, the pharmacy community itself is the direct beneficiary of PRC activities extended on behalf of impaired practitioners. Thus, it is reasonable that individual donors, including those who have benefited directly from the Committee's actions, and contributions from pharmacy associations should continue to be the base of the PRC's financial support. Appropriate cost sharing, rather than reliance upon state funds, is the goal of the Committee's budget.

It is important for the PRC to maintain a dialogue with the community of pharmacy practitioners. Since its origination in 1983, the PRC has been working to lower the barriers that prevent impaired pharmacists from accessing services known to be effective in the treatment of chemical dependence. Unfortunately, even with aggressive efforts some individuals are unsuccessful in attempts to achieve sobriety. Outreach efforts are focused on: continuing education programming which improve understanding of the nature of drug dependence and its treatment; increasing the rate of treatment referral; and enhancing post-treatment employment opportunities.

Ultimately, a healthy and vibrant program requires the philosophical as well as the financial support of its constituency. **MP**

Editor's Note: Volunteerism is the foundation of the Pharmacists Rehabilitation Committee. The PRC is composed of pharmacists who devote a considerable amount of time and effort in service to their colleagues through the process of intervention, referral and follow-up. Pharmacists wishing to offer their services, or who require assistance with self, friends, colleagues, etc., should contact the chairman at (410) 706-7513.

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PRO

Compounding should remain a part of Maryland's pharmacist licensure examination!

*David Robinson, MPhA Intern
Third Year Student, Howard University*

There is a great debate going on in the state of Maryland between the students that wish to do away with the compounding portion of the state Board Examination, and the state Board which is reluctant to grant that wish. Over forty other states have done away with the "wet lab", and through this action are conveying the message that the NABPLEX examination and knowledge of state law is sufficient for students aspiring to become pharmacists. Compounding accounts for less than five percent of all prescriptions filled by today's pharmacists. Even though the percentage of compounded prescriptions is less than it was a few years ago, the importance of the pharmacist's *ability* to prepare

a compound hasn't decreased. Compounding medications has been and will continue to be an integral part of the profession.

The art of compounding is still an important aspect of the practice of pharmacy and the Maryland Boards should reflect that importance. Students should be required physically prepare a compound. Should Maryland base its decision to discard the wet lab solely on the judgment of the majority of other states? I don't think so. The Board of Pharmacy has a responsibility to protect its citizens from incompetent individuals seeking a license to practice pharmacy. Can you imagine the possibilities for errors in compounding a prescription just in the retail setting? If a community pharmacist dispenses the wrong tablet or capsule to one of his or her regular patients, chances are that the patient will recognize an error in the dosage form, shape, or color of the medication received and bring it to the attention of the pharmacist. The pharmacist can then make the correction and apologize for the error. This situation would have a totally different outcome if the pharmacist makes a compounding error. The patient will not be able to recognize an error made by the pharmacist because he/she has no point of reference to compare the product to. The result will be therapeutic failure and possibly toxic effects.

Many students argue that they are not against compounding, they're only against compounding being a requirement on the Board Examination. I would argue that the only way the State can reassure its citizens that pharmacists practicing in Maryland are competent in all areas of pharmacy is to continue to require a compounding assessment. I believe that the Board Board should also make compounding a requirement for licensees seeking reciprocity to practice in Maryland. The Board should also take into account the fact that the percentage of actual compounding pharmacists is down from previous decades and this should be reflected in the way that compounding portion is graded.

Students against compounding on the boards will also argue that questions regarding compounding are included in the NABPLEX examination and are similar in format to problems included in the School of Pharmacy courses. Solving compounding problems mathematically does not determine whether or not a pharmacist can make the finished product using proper techniques such as levigation, trituration, the aliquot method and geometric dilution. Furthermore, if the same students were informed about the intentions of Dr. David Kessler, Commissioner of the United States Food and Drug Administration, to define compounding as the manufacturing of a new drug and therefore requiring FDA approval, they would be the first to defend the rights of the pharmacist to compound based on the fact that we've been doing so for thousands of years. Students will defend or refute compounding based strictly upon whether or not it's in their best interest.

MP

As the pharmacy profession moves into the 21st Century, it will be required to make many changes in its practice setting, both from within and without. From reimbursement for cognitive services to technician certification, the profession must adapt or face the possibility of becoming extinct.

Compounding should be removed from Maryland's pharmacist licensure examination!

*Aatif Sheikh, MPhA Intern
Second Year Student, UMAB*

One way innovation which would acknowledge the changing environment is the removal of compounding from the Maryland Pharmacy Licensure Examination. Compounding means "the preparation, mixing, assembling, packaging, or labeling of a drug or device, (1) as the result of a practitioner's prescription drug order or initiative based on the pharmacist/patient/prescriber relationship in the course of professional practice; or (2) for the purpose of, as an incident to research, teaching, or chemical analysis, and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of Prescription Drug Orders based on routine regularly observed patterns."¹

In the past, compounding was a major part of the pharmacist's workload, but with modern technology and the rise of industry, this is no longer the case. When discussing compounding, Dean King, executive vice president of Professional Compounding Centers of America states, "Fifty years ago, pharmacists did their own compounding for at least 60 percent of all prescriptions. Since then, drug manufacturers have made advances in packaging, preserving, shipping, and delivery that have reduced individual compounding to less than 5 percent of all prescriptions."² Although compounding is still a part of the pharmacy profession, and should remain so, the emphasis placed upon it by the Maryland Licensure Examination seems inordinant.

Perhaps one of the strongest arguments for the removal of compounding from the Maryland Exam is the fact that only eight states currently require a separate test for compounding skills. They are: Maryland, Wisconsin, New York, Georgia, North Dakota, North Carolina, Minnesota, and Kentucky. However, in Minnesota and Kentucky the exam taker need only write how they would compound the prescription, there is no actual compounding. Most states believe that the NABPLEX is sufficient to test compounding ability.

Since most states do not require a "wet lab," it seems logical that individuals who wish to avoid a compounding examination could take the Boards in another state and then reciprocate to Maryland. Keep in mind that the only requirement for Maryland reciprocity is to take and pass the Maryland law examination and have 520 hours of experience.

Another failing of Maryland's compounding exam is that the same compounds are given to the test takers every year. Although not the same prescriptions, the test taker can count on getting one ointment, one solution, one antibiotic suspension, and one capsule. This means that the examinees need only know how to prepare these four compounds in order to pass the exam. This is clearly not a sufficient test of one's ability to compound. Most pharmacists obtain basic compounding skills during their education and really learn compounding once they get out into practice.

Some pharmacists feel that since compounding has always been on the state exam it should remain, if only for reasons of tradition. However, with the changing scope of pharmacy, perhaps it would

Concluded on following page....

better serve the pharmacy community to offer another type of practical exam instead of compounding. One suggestion would be to give each examinee ten prescriptions and ask them what if anything was wrong with the prescriptions. This would satisfy those that say the compounding exam is not really to test compounding but more of a test of the examinee's technical skills in reading and following the directions on a prescription. Another idea would be to make compounding a specialty practice like nutrition or pediatrics. A specialty practice would allow those pharmacists who wish to compound an avenue to pursue it further while at the same time making those prescriptions which are compounded safer for the general populace.

In conclusion, by replacing the compounding portion of the Maryland State Board exam with a different type of practical exam that assesses more widely used aspects of pharmacy, pharmacists can lead the way in changing the profession of pharmacy. As pharmacists, it is our right to compound; however, in a time when compounding has become less than five percent of the prescription load making it a separate part of the Board exam in Maryland seems excessive. **MP**

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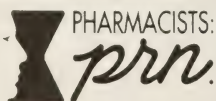
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Litigation Update

Utilization Review and Confidentiality

With more and more third-parties and managed care entities requiring the collection, processing and review of confidential prescription information, what is the pharmacist's responsibility in protecting that data?

An employee of a regional transportation authority brought a lawsuit against his employer for violations of his civil rights by both the employer and an official who worked for the employer. The lawsuit arose from an incident in which the official and others who also worked for the employer learned that the employee was HIV positive, based on a review of utilization reports of the employer's prescription drug program.

Before filling his prescriptions, the employee asked his supervisor, the head of the employer's medical department, whether anyone audited the prescriptions filled under the employer's benefit plan in such a way that people's names were associated with the drugs they were taking. The supervisor stated that he had on occasion been asked to look at prescription records when someone was suspected of abusing a narcotic, but that otherwise the prescription records were not examined in such a way that names were associated with drugs or diagnoses.

Two years later, after changing pharmacy providers, the employer was provided with a utilization report that included employee names and the drugs they were prescribed as well as the cost of the prescription and the date it was filled. Through her view of this report, the official learned that the employee was HIV positive. This information was shared with at least three other employees in a way that highlighted the information about the employee's HIV status.

In the lawsuit that ensued, the court ruled that, particularly in light of the hysteria surrounding HIV and the employee's documented efforts to keep the information confidential, "the information contained in the prescription benefit utilization report was well within his reasonable expectations of confidentiality and thus was protected by the constitutional right to privacy."

A verdict in the amount of \$125,000 was entered by the court.

Although the pharmacy that provided the utilization review information to the employer was not made a party to this litigation, this lawsuit is a reminder that only those people having a "need to know" confidential information should be given it. In this case, the court specifically ruled that the official supervising the drug use review had no "need to know" patients' identities. MP



David B. Brushwood, R.Ph., J.D.

Based on: Doe v. Septa, 1995 Westlaw 334290 (E.D.Pa. June 2, 1995).

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Continuing Education

New Drugs Review: Alzheimer's and Tacrine

*Thomas A. Gossel, R.Ph., Ph.D., Dean
Ohio Northern University*

*J. Richard Wuest, R.Ph., Pharm.D.
Professor of Pharmacy Practice, University of Cincinnati*

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Alzheimer's disease dementia, named for the German neurologist who first described the condition in 1906, is a progressively degenerative disease that damages the brain and causes impaired memory and behavior. It eventually results in death due to failure of the organs innervated by the diseased portions of the patient's brain. The course of the disease, once symptoms appear, is usually two to ten years. It results in the inability of victims to care for themselves in its later stages.

The statistical data associated with Alzheimer's disease are staggering. According to the Alzheimer's Disease and Related Disorders Association, approximately four million Americans have the condition. It is estimated that this will rise to 14 million midway through the next century if a cure is not found.

Alzheimer's disease is the fourth leading cause of death (100,000/year) among adult Americans. While the disease principally affects persons over 65, it does occur earlier in life. However, after age 65, one in 10 persons and nearly 50 percent of those over age 85 have Alzheimer's disease.

The disease costs society approximately \$100 billion a year. Since neither Medicare, nor private insurance companies covers the type of care most Alzheimer's disease patients need, most of the cost is borne by the family of the victims. These costs are estimated at \$18,000/year for

home care and \$36,000 to \$75,000/year for long term care facilities.

Although this disease was described nearly 90 years ago and similar cases were seen numerous times over the years, it was regarded mainly as a symptom of old age until the 1960s. This was due to advancements in the use and capabilities of electron microscopes in the study of disease states.

By 1976, scientists had discovered that Alzheimer's disease was caused by a neurochemical deficiency in the brain. As with Parkinsonism, schizophrenia, depression, and other mental disorders, this breakthrough opened the door for studying Alzheimer's disease as a specific disease, separate from the normal aging process.

As a side note, there was no tremendous groundswell of sensitivity toward Alzheimer's disease victims and their families until Abigail van Buren answered a question about where to find information on Alzheimer's disease in her "Dear Abby" column in the 1970s. Her reference to a fledgling Alzheimer's disease support group, which at that time had only seven chapters and 700 members, brought in tens of thousands of letters asking for more information.

According to the organization, this helped increase interest and advocacy for Alzheimer's disease research and support leading to today's international organization operating in 28 countries. By 1994 in the United States, the Alzheimer's Disease and Related Disorders Association had more than 220 chapters, 35,000 members, and 2,000 local support groups.

Dementias

Alzheimer's disease is one of several dementing disorders. Others are caused by cardiovascular diseases such as atherosclerosis and myocardial infarction; metabolic disorders such as hypothyroidism, hypoglycemia, hyperlipidemia and systemic lupus erythematosus; organ disorders such as liver, lung and kidney disease; and infections diseases such as AIDS, encephalitis, meningitis, and syphilis.

Other types of dementias result from degenerative disorders such as Parkinsonism, Gaucher's disease, and Huntington's disease. Cancer, alcoholism, carbon monoxide, other toxic chemicals, and many other conditions lead to dementias as well.

Similar to other dementias, patients with Alzheimer's disease progressively lose short-term memory, speaking skills, and the ability to perform abstract thought processes. These worsen continually, eventually causing permanent changes which interfere with self-care and routine daily activities. As the disease continues, patients suffer from deliria and depression concurrently.



Patients get lost. They suffer poor job performance, cannot carry on a conversation, and lose interest in social contact. In the next stage of deteriorations, knowledge of current events and personal and family history deteriorates, as well as the ability to perform simple tasks, such as mathematical calculations, and later more complex ones. During this time, most patients are anxious and deny that they are having problems.

The next stage is loss of memory of names, phone numbers, addresses, social security numbers, and disorientation to time and place. This advances to unawareness of the patient's environment and recent events. Delusions, severe anxiety and possibly violent behavior frequently follow.

In late dementia, patients lose the ability to feed themselves, dress, verbalize, and maintain continence. Death ensues within months to several years.

Risk Factors for Alzheimer's

While the exact cause of Alzheimer's disease has not yet been determined, there are a number of risk factors that may contribute to its occurrence. These have been reported to be genetics, toxins, trauma and vascular disease.

Genetics. Certainly Alzheimer's disease can occur in anyone, but there is evidence that a family history of the disorder is the most consistent risk factor, increasing the potential 400 percent. Several years ago, scientists believed they had discovered the gene that causes Alzheimer's disease.

It is now felt that, while there

is an association with a gene defect (known as chromosomal Alzheimer's disease amyloid precursor), an absolute link between the activity of this gene and all cases of Alzheimer's disease has not been proven.

Head trauma is another risk factor for the development of clinical signs of dementia including Alzheimer's disease. It has been proposed that, while trauma is not the cause of Alzheimer's disease, head injury can accelerate its development by five to seven years.

The **toxin** most associated with Alzheimer's disease is aluminum, which is the most abundant metal in the earth's surface. The human body has efficient mechanisms to prevent its entry and significant accumulation. Nonetheless, for several years it was believed that aluminum accumulation played a role in Alzheimer's disease. More recently strong contradictory data has been uncovered and the association is no longer a popular believe. It is true that ionic aluminum inhibits many enzyme systems and that its application directly to brain tissue does induce degeneration. However, the dementia that follows does not resemble Alzheimer's disease.

Vascular disease appears to be a contributory risk factor to Alzheimer's disease. Patients with coronary artery disease and previous myocardial infarction are considered to have a six-fold greater chance of developing Alzheimer's disease.

Diagnosing Alzheimer's

Several abnormalities in the brain are associated with Alzheimer's disease, most specifically clusters (plaque) of what is called amyloid protein as well as cortical neurofibrinous tangles (bundles). Patients with Alzheimer's disease invariably have deposits of dense clusters of amyloid in the brain. These are thought to damage adjacent nerve endings and render them useless.

However, amyloid plaques are no longer considered to be the sole cause of Alzheimer's disease. In the last few years, autopsies have identified significant numbers of individuals whose brains had enough plaque to meet the criteria for Alzheimer's disease, but had no noticeable cognitive impairment.

The bottom line at this point is that most patients with Alzheimer's disease, on autopsy, show numerous plaques high in amyloid content and bundles of neurofibrils. These are considered to be the major diagnostic indicator of Alzheimer's disease. Unfortunately, the reality is that under normal conditions the plaque and bundles can only be discovered after the patient's death.

As stated earlier, Alzheimer's disease is one of dozens of dementias. However, it is reported that at least 75 percent of demented patients have Alzheimer's. While definitive diagnosis is based on histological changes in brain tissue seen on autopsy, there are several guidelines that differentiate Alzheimer's disease from other dementias which can be applied while the patient is alive.

Criteria for Alzheimer's Disease

I. DSM-III-R Criteria (adapted)

- A. Demonstrable evidence of impairment in short- and long-term memory, and at least one of the following is present:
 - * Impairment in abstract thinking (e.g., inability to find similarities and differences between related words, difficulty in defining words and concepts).
 - * Impaired judgement (inability to make reasonable plans with interpersonal, family or job-related problems and issues).
 - * Other disturbances of higher cortical function.
 - * Personality change.
- B. The impairment or disturbance significantly interferes with work or usual social activities or relationships with others.
- C. The impairment or disturbance does not occur exclusively during the course of delirium. Either of the following occur:
 - * There is evidence from the history, physical examination or laboratory tests of a specific organic factor(s) judged to be etiologically related.
 - * In the absence of such evidence, an etiologic organic factor can be presumed if the disturbance cannot be accounted for by a nonorganic mental disorder (e.g., major depression).
- D. Insidious onset with uniformly progressive deteriorating condition.
- E. Exclusion of all other specific causes of dementia by history, physical examination and laboratory tests.

II. NINCDS/ADRDA Criteria (adapted)

- A. Criteria for clinical diagnosis of probable Alzheimer's disease:
 - * Dementia established by clinical examination, documented and confirmed by standardized tests.
 - * Deficits occurring in two or more areas of cognition (memory, calculation, judgement, etc.)
 - * Progressive worsening of memory and cognitive functions.
 - * No disturbance of consciousness.
 - * Onset between ages 40 and 90.
 - * Absence of systemic disorders, or other brain diseases that could account for progressive deficits.
- B. Diagnosis is supported by the following:
 - * Progressive deterioration of specific cognitive functions.
 - * Impaired activities of daily living and altered patterns of behavior.
 - * Family history of similar disorder.
 - * Normal, nonspecific changes in EEG.
 - * Evidence of cerebral atrophy, with documented progression.

Please see text for sources.

Table 1

One set of criteria is the Diagnostic and Statistical Manual Volume III Revised (DSM-III-R). Another set is the National Institute of Neurological and Communicative Disorders and Stroke/Alzheimer's Disease and Related Diseases (NINCDS/ADRDA). These criteria are outlined in Table 1.

Even though the exact cause of Alzheimer's disease has not yet been elucidated, there are strong implications that there is no single factor involved. There appear to be multiple mechanisms that initiate the disease. This means that Alzheimer's disease is not likely to be cured or prevented by controlling only one causative factor in all patients.

It also means that in the full spectrum of Alzheimer's disease patients, there are sub-groups that will undoubtedly respond to one type of therapy and not others, and there will be a sub-group of patients who will require multi-agent treatments when they are discovered.

Since there appears to be several causative factors leading to Alzheimer's disease, drug therapy is multifaceted. Paramount among this is treatment of anxiety, restlessness, psychoses, agitation, sleep disorders, aggressiveness, and depression that affect the patient, family members, and care givers. Among the agents used are the anxiolytics, antidepressants, neuroleptics, and psychostimulants. Ergoloid mesylates, pentoxifylline, and calcium channel blockers are used in an attempt to increase blood flow and oxygen supply to brain cells.

However, since cholinergic deficit in the brain appears to be a component of Alzheimer's disease, this article will zero in on the first drug approved for specific use in its treatment, the cholinesterase inhibitor tacrine.

Cholinesterase Inhibitor Therapy

The group of drugs that has shown at least moderate beneficial effects in a subpopulation of patients with Alzheimer's disease is the cholinesterase inhibitors. The first drug in this group to be approved for marketing is tacrine (Cognex).

The areas of the brain most affected in Alzheimer's disease are the hippocampus and cortical areas, which are involved in the integration of information from sensory input. Here is where we relate input to prior life experiences (memory) so we can deter-

mine how we will perceive what we hear, see, smell, taste, and touch. This is why loss of short- and long-term memory are among the early indicators of Alzheimer's disease.

The above areas have a very high concentration of cholinergic cells and nerve endings. Their destruction is a major factor in memory loss. Drugs that can reduce further deterioration and enhance the activity of those that remain are considered useful in helping restore memory and possibly deter the advance of Alzheimer's disease.

Tacrine (ta-KREEN) - Cognex (cog-NEX) is a centrally acting cholinesterase inhibitor. Its mechanism of action in Alzheimer's disease results from its ability to slow the breakdown of acetylcholine produced by functioning cholinergic neurons in the brain. Other, possibly contributory activities attributed to tacrine are its partial stimulation of cholinergic receptors; as well as mild reuptake blockade of norepinephrine, serotonin, and dopamine; monoamine oxidase inhibition; and blockade of sodium and potassium channels.

The acetylcholine-sparing activity of tacrine moderately restores memory in some patients with Alzheimer's disease. Its manufacturer is straightforward in pointing out that the drug is not effective in all patients. There is no evidence that the drug affects

the underlying condition or alters its course. Since the drug relies on the integrity of cholinergic activity, tacrine therapy will, at some point, become ineffective as the disease process progresses.

The upside to the use of tacrine is that for those patients for whom it is effective, it improves memory and other symptoms of Alzheimer's disease. It allows these patients to communicate with family and friends during a period of time they would not be able to if untreated. And, it makes them less of a burden on those providing their care during this period of time.

The rate of absorption of tacrine is variable among patients receiving it. Taking tacrine with food reduces plasma levels 30 to 40 percent. This can be prevented by taking the dose one hour before meals and at bedtime. However, if GI upset occurs, the dose can be taken with food to improve tolerability and compliance.

Drug Interactions

Since tacrine is a cholinesterase inhibitor, it is expected to increase the activity of other cholinergic drugs. The most significant drug interaction described is the potential for an exaggerated response to the surgical muscle relaxant succinylcholine.

Tacrine has the potential to interfere with anticholinergic drugs, but no significance has been demonstrated to date.

Tacrine

| Generic | Trade Name | Availability | Dosage Regimen |
|---------|------------|-------------------------|---|
| Tacrine | Cognex | 10, 20, 30 40mg caps | 10mg QID for 6 weeks weeks, then titrate upward to 40mg QID |

Tacrine is metabolized extensively by the cytochrome P450 enzyme system utilizing the same isozyme as does theophylline. Its manufacturer warns that the coadministration of tacrine and theophylline may decrease the latter's clearance and raise its plasma levels approximately two-fold. It advises that when these are used concurrently, theophylline plasma concentrations be monitored and the dose reduced as needed.

Cimetidine can increase plasma levels of tacrine, but the significance of this is unknown. Drugs that have been studied but not shown to interact significantly with tacrine are warfarin, digoxin, benzodiazepines, and antacids.

Side Effects

The primary adverse effects seen with tacrine relate to its cholinergic action. These include GI symptoms, agitation, urinary frequency, and increase sweating. Rarely, hypotension and bradycardia have been seen. All of these can be lessened by starting with low doses of 10mg four times a day and titrating the dose upward of several months to 40mg four times a day.

The most serious adverse effect associated with tacrine is the risk of liver toxicity. While the occurrence of clinical hepatotoxicity is relatively rare (less than eight percent of patients), approximately 50 percent of patients in tacrine pre-marketing trials experienced elevated alanine aminotransferase (ALT) levels. This enzyme was known previously as serum glutamic pyruvic transaminase (SGPT). Elevated ALT does not mean that liver toxicity will occur, but it is a warning sign that it may.

Therefore, serum alanine aminotransferase levels should be monitored weekly during tacrine therapy. Physicians use dosing guidelines based on ALT results. In most instances, these levels return to normal after a drug-free period. Then, when the patient is given the drug again, 88 percent can tolerate it with no further problems with elevated ALT.

Side effects reported by the manufacturer at the 9 percent or higher level are: elevated transaminase, 29 percent (vs 2 percent for placebo); nausea and/or vomiting, 28 (vs 9) percent; diarrhea, 16 (vs 5) percent; dizziness, 12 (vs 11) percent; headache, 11 (vs 15) percent; dyspepsia, 9 (vs 6) percent; muscle pain 9 (vs 5) percent; and, anorexia 9 (vs 3) percent.

Dosage

The recommended dose of Cognex is 10mg four times a day for a minimum of six weeks with weekly monitoring of ALT levels. Provided there is no significant ALT elevation during this time, the dose is increased to 20mg four times a day for another six weeks. The dose is then titrated upward at six week intervals to the optimal dose, usually 40mg four times a day.

Once the patient is stabilized, tacrine should not be discontinued abruptly due to the potential for a decline in cognitive function and behavioral disturbances. Changes in dosage should be under the direct instruction and supervision of a physician.

Additional information useful is counseling patients and caregivers on the use of Cognex is listed in Table 2.

MP

Patient Information for Cognex

Cognex is used to treat symptoms of Alzheimer's disease and other conditions as determined by your doctor.

- This leaflet is intended to help assure Cognex is taken correctly, not to be confusing. If the doctor has told you something different, follow those instructions.
- Cognex should be taken four times a day, between meals, and at bedtime with a full glass of water. If stomach upset occurs, the capsules may be taken with meals.
- It is important that Cognex be taken exactly as the doctor has instructed. Do not skip a dose, change the amount, or stop taking it without consulting the doctor.
- If a dose of Cognex is missed, it should be taken as soon as possible. But, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not give the patient a double dose, unless directed by your doctor.
- Every medication is capable of producing side effects. Most patients experience few problems while taking Cognex. However, be sure to tell the patient's doctor if the following occur: severe nausea, vomiting, diarrhea, skin rash, muscle pain, abdominal pain, severe headache, swelling of the extremities, yellowing of the skin, persistent sore throat, excessive dizziness and agitation, difficulty in sleeping, runny nose, changes in stool color (either very dark or very light) or any other unusual, bothersome effects.

Adapted from the Pharmex PALs (Patient Advisory Leaflets). For more information, call 1-800-233-0585.

Table 2

Continuing Education Quiz

September 1995 -- Alzheimer's and Tacrine

This month's questions are taken from the article on Alzheimer's disease and tacrine that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. There is **no charge** for this quiz for MPhA members (non-members \$5.00). The completed quiz for this issue must be received by February 28, 1996. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly. **ACPE # 186-144-95-023**

Name _____

Address _____

City/State/ZIP Code _____

1. The breakthrough that opened the door for studying Alzheimer's disease as a specific disease, separate from the normal aging process, was the discovery that it was caused by a:
 - a. a bacterial infection
 - b. viral infection
 - c. neurochemical deficiency
 - d. vitamin deficiency
2. The toxin most associated with, but not yet proven to be linked to, the development of Alzheimer's is:
 - a. aluminum
 - b. chromium
 - c. selenium
 - d. zinc
3. Patients with Alzheimer's disease invariably have deposits of dense clusters of which of the following substances in the brain?
 - a. Aluminum
 - b. Amyloid
 - c. Asbestos
 - d. Cholesterol
4. Autopsies have shown that individuals whose brains had enough plaque to meet the criteria for Alzheimer's disease:
 - a. always had cognitive impairment.
 - b. sometimes had no noticeable cognitive impairment.
5. While not yet approved for the indication, calcium channel blockers and pentoxifylline are used in patients with Alzheimer's disease in an attempt to:
 - a. reduce the occurrence of Parkinsonian symptoms.
 - b. increase cardiac output and stroke volume.
 - c. reduce disease-related anginal attacks.
 - d. increase blood flow and oxygen to the brain.
6. Tacrine's mechanism of action is attributed to its inhibition of:
 - a. carbonic anhydrase
 - b. monoamine oxidase
 - c. cholinesterase
 - d. phosphodiesterase
7. The neurotransmitter affected to the greatest extent by tacrine is:
 - a. acetylcholine
 - b. dopamine
 - c. norepinephrine
 - d. serotonin
8. The ideal dosage regimen for tacrine is:
 - a. once daily in the morning
 - b. twice daily
 - c. three times a day
 - d. one hour before meals and at bedtime
9. The most serious adverse effect associated with tacrine is:
 - a. cardiotoxicity
 - b. hepatotoxicity
 - c. nephrotoxicity
 - d. ototoxicity

CLASSIFIED ADS

Services

20% DISCOUNT on awards, plaques, trophies, and engraving to MPhA members. Call Rudy Winternitz, P.D. at Washington Trophy Center, (202) 966-1255.

BILLING PROBLEMS? We are "the" experts in problem reimbursement. We have over a dozen years experience in the pharmacy billing field, and seven in the infusion/home care industry. Even if you think your practice is going well, let us give you an estimate of how we can increase your reimbursement. Call now for a prompt, professional and personal billing service. Call (410) 282-0285.

PHARMACISTS: prn PLACEMENT AGENCY for temporary and permanent placement. Find out why more and more pharmacies are turning to PHARMACISTS: prn to fill all of their pharmacy staffing needs. Only 10% permanent placement fee, with 60 day guarantee. Temporary staffing services also available. Competitive prices. Rates for temps include all payroll taxes, FICA, workers' comp, liability insurance, etc. Almost a decade in providing pharmacy personnel services in every practice setting. Call PHARMACISTS: prn at (800) 832-5560.

THINKING ABOUT MOVING to South Florida? Retiring or looking for a winter home. Now is the time to buy. Let me put you in your dream home. Maryland pharmacist now Florida realtor, affiliated with one of the top independent real estate firms. Let us do the looking for you. Call Gary Taylor, Contemporary Realty (800) 635-4486. Home: (407) 369-1393, FAX: (407) 790-9249.

WHAT DO STEAMED CRABS, the Orioles and *PharmaSTAT* have in common? They're all superior local products that cannot be duplicated outside of Maryland. *PharmaSTAT* is a Maryland company that has been providing quality pharmacists to Maryland pharmacies for 9 years. We have the largest active pool of pharmacist in the state, and have a proven track record. FT & PT pharmacists are available. Guaranteed lowest rates in the state! Need a pharmacist? Call *PharmaSTAT* at (410) 659-STAT.

PHARMACISTS REHABILITATION COMMITTEE For private, confidential referrals call (410) 727-0746 or (410) 706-7513.

Rx LICENSE TAGS are still available! A special benefit "for members only" that costs only a nominal fee. If interested, call Mary Ann at the MPhA offices toll-free, (800) 833-7587.

CAPITATION How is it treating you? Our top earners average \$700,000 per year. Rock solid company with cutting edge products used by Olympians and hundreds of physicians. Made for professionals caught in a challenging time; we are your answer to capitation. Call (410) 740-7165.

KIRBY LESTER KLS FOR SALE tablet counter. Just reconditioned by manufacturer. Perfect operating condition. Will ship! \$450. Call (800) 231-1190.

Positions

PHARMACISTS Join Maryland's oldest and largest pharmacist agency -- *PharmaSTAT*! FT & PT opportunities are available now. Enjoy flexibility, excellent pay rates, benefits and cash bonuses. We offer jobs, not empty promises. Join *PharmaSTAT*! For information call (410) 659-STAT.

PHARMACIST AVAILABLE Bethesda pharmacist available for occasional relief. Weekends or evenings after six. Strong counseling skills. Prefer independent. Willing to travel on weekends. Call (301) 215-6775.

LICENSED PHARMACISTS Full- and part-time positions available in various Baltimore locations. Management background a plus. Positions may lead to various management career paths. Benefits include: medical package, flexible spending accounts for non-covered health and dependent care expenses, term life, and accidental death and dismemberment coverage, 401(K) plan, CE programs. Send resume to: Giant Discount Drug, Dept 541, PO Box 1804, Washington DC 20013 or call (301) 341-8700, ext. 1428. EOE.

PHARMACY JOB OPPORTUNITIES

Full and part-time, permanent and temporary, competitive pay and excellent benefits (accrued vacation pay, direct deposit, bonus plans, liability insurance, temporary health package, 401(k) plan, etc.) Positions in all practice settings. For more information, call PHARMACISTS:prn at (800) 832-5560.

PHARMACIST WANTED Evening (5-8 pm) pharmacist needed. Must have strong counseling skills and enjoy compounding. Name your hours - days - and pay rate (within reason). Call (410) 757-3522. Cape Drugs, Cape St. Claire Road, near Annapolis.

Placing an Ad

Have something to sell, rent, or trade? Need a pharmacist? Looking for a new position? MPhA members can place a classified ad in *The Maryland Pharmacist* for free. MPhA will remove member ads after six months unless otherwise notified by the member. Non-members may also place a classified ad. The ad placement charge is \$10 for a maximum of 50 words plus 50 cents per word greater than 50. To place an ad, call MPhA at (800) 833-7587.

Rentals

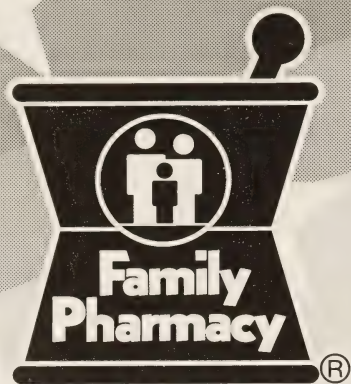
OCEANFRONT OC CONDO Fully furnished, 2 BR, 2 BA, cable TV, VCR, W/D, indoor pool, lighted tennis courts, sauna, gameroom. Convenient location, Seawatch at 115th Street. Great off season rates, call now for more information, (410) 647-6924.

Important Numbers

MPhA Offices
(410) 727-0746
(800) 833-7587 toll-free in Maryland
(410) 727-2253 FAX

MSHP Offices
720 Light Street
Baltimore, Maryland 21202
(410) 752-3318
(410) 752-8295 FAX

Maryland State Board of Pharmacy
4201 Patterson Avenue
Baltimore, Maryland 21215
(410) 764-4755
(800) 735-2258



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AmeriSource

NEWSLETTER

The Maryland Pharmacists Association

650 Lombard Street

Baltimore, Maryland 21201

(410) 727-0746

Welcome New Members

A special "hello" to 30 new MPhA members:

| | |
|-----------------|----------------------|
| Emmanuel Anozie | Brian Chivers |
| Terry L. Davis | Ruth Davis |
| Jeanne Elliott | John Freeman |
| Marsha Friedman | Matthew Green |
| Sarah Kang-Pak | Alfred Lawson |
| James Lee | Valetina Lvovsky |
| Mary Ann Malia | Michael Marcus |
| David Marini | Pina Mercer |
| Mark Miller | Arnold Neuberger |
| Mary Jo Nguyen | Barbara Objinski |
| Richard Parker | Faxalur Rehman |
| Brent Rhoads | Renee Rockman |
| Edwin Schneider | Kathleen Shaughnessy |
| Sundus Sleiman | Karla Tirimacco |
| Marcel Uzowihe | Kimberly Zimcosky |

PTCB Examination

The first PTCB certification examination was taken by 2,492 pharmacy technicians nationwide on July 29. Of those, 2,090 (84%) passed. The technicians came from all areas of practice but most were from community and hospital pharmacies.

Beginning in 1996, the Maryland Pharmacists Association will join forces with the Maryland Society of Health-System Pharmacists in promoting the Pharmacy Technician Certification Examination. The 1996 test dates are: March 23, July 27, and November 2. Handbooks and registration materials for these dates will be available from MPhA in late November.

October 1995

The MPhA Newsletter is published monthly except during the months of July and August when the issues are combined. For information about any article contained herein, contact MPhA at (410) 727-0746 or toll-free at (800) 833-7587. President: James Tristani, P.D.; Chairman, Board of Trustees: Arnold Davidov, P.D.; Production Manager: David Miller, P.D..

Medicaid Block Grants

By a vote of 27 to 18, the House Commerce Committee has recommended the abolishment of federal guarantees of Medicaid benefits and the establishment of a new "MediGrant" program -- a system of lump sum cash grants to the states. A key element of the Republican effort to rein in expenditures in the federal Medicaid program, block grants are designed to slow the Medicaid growth rate from the current 10.4 percent a year to four percent annually by 2002.

Currently, Medicaid is a combined state and federal program of which the federal government divides \$89 billion among the states. Under "MediGrants," states would have the flexibility to administer the grants with minimal federal oversight. And, since states are assumed to have a greater efficiency in managing programs on a local level, the amount of money spent by the feds would gradually decrease.

The proposed reductions in Medicaid resources, if they do come to pass, will probably have a disproportionate effect on the disabled and elderly. This group accounted for 60 percent of Medicaid expenditures last year but make up only 30 percent of the beneficiary population. The Urban Institute reports that if the proposed level of Medicaid cost is achieved, 8.8 million beneficiaries could become ineligible, and many currently required services, such as health screenings and home care, could be eliminated.

Block grants could have a devastating impact on pharmacists. It's highly likely that "MediGrants" would also result in a repeal of the Boren Amendment which requires that payments be "reasonable and adequate" to meet congressionally mandated standards of care. The Boren Amendment requires states to take into account the costs of complying with federal law when determining payment levels to Medicaid providers. Also, enactment of block grants would undo or revise the nursing home standards and reforms enacted as part of OBRA '87. OBRA '87 is vitally important to consultant pharmacists; its repeal would eliminate federally mandated pharmacy services such as drug regimen review for nursing home residents.



State Contract Goes to PAID/Medco

Governor Glendenning has signed a contract with PAID/Medco to administer the State Employees Prescription Drug Benefit beginning January 1, 1996. PAID's winning bid of \$266 million was substantially lower than current administrator PCS and the more than eight other bidders. MPhA has received confirmation that the plan will provide mail-order delivery as an *option*; it will not economically discriminate against employees and retirees who prefer to use their local pharmacist. A new PAID contract for this group, which will be available to all Maryland pharmacies, will be distributed soon. MPhA will keep you apprised.

Berkowitz Selected for Award

MPhA member **Lance Berkowitz** has been selected as the 1995 national recipient of the *U.S. Pharmacist* "Service to the Community Award." The award includes a \$1,000 scholarship to the college of pharmacy of his choice and a \$1,000 grant to a major national pharmacy association. Berkowitz, a past-president of the Baltimore Metropolitan Pharmacists Association, will receive his honor during ceremonies at the Ritz-Carlton Hotel in Arlington, VA early in November.

West Retires

After more than eleven years of dedicated service, NARD Executive Vice President Charlie West is retiring from the organization. West had previously served as Executive Director of the Arkansas Pharmacists Association. Former NARD President Calvin Anthony of Oklahoma has been named as West's successor.

No Need for Third-Class of Drugs

A major pharmacy issue has been the establishment of a separate class of drugs that would be available only through pharmacies. A popular past suggestion has been that a pharmacy-only category could be used as prescription items transition to over-the-counter status. Traditionally, OTC manufacturers have been the major opponents to such a class. Add one more.

The US General Accounting Office (GAO) released a report in August entitled *Non-Prescription Drugs: Value of a Pharmacy-Controlled Class Has Yet to be Determined*. The study, requested by Congressman John Dingell (D-MI) with the support of many pharmacists, assessed the need for creating a new class of drugs that would be available without a physician's prescription. The reviewers considered the distribution systems of 10 other countries and the European Union. The conclusion of the study was that little evidence supports the establishment of a pharmacist class of drugs in the US. To request a free copy from the GAO, send a written request by FAX to (301) 258-4066.

Missing Money

Notice anything unusual about your reimbursement for Medicaid recipients in Chesapeake Health Plan? Look a little closer and you may discover that Chesapeake unilaterally reduced dispensing fees on or about July 1.

Sharp-eyed MPhA member **Don Schumer** caught the reduction recently. After some investigation, it was determined that Chesapeake had reduced the fee and had violated its own contractual obligation that no change in the contract's terms "shall be valid unless agreed to in writing."

MPhA attorney Joe Kaufman has initiated action against Chesapeake and their claims processor Express Scripts on behalf of all members.

Missing More Money

If you fill prescriptions for Kaiser Permanente, you better take a second look at your recent payments. Claims submitted to Kaiser since early June may or may not have been paid. Kaiser doesn't know because, as they claim, they've been converting over their computers during the past "several months."

If you have outstanding Kaiser claims, they must be submitted by hand on universal claim forms to: Kaiser Accounts Payable, Attn: Debbie Boyd, 2101 East Jefferson Street, Rockville, MD 20849.

Upcoming Health Events

Telephone numbers are provided for additional information and promotional materials.

November

| | |
|-------------------------------------|----------------|
| Alzheimer's Disease Month | (312) 335-8700 |
| Diabetes Month | (703) 549-1500 |
| Epilepsy Month | (301) 459-3700 |
| Hospice Month | (202) 546-4759 |

December

| | |
|--|----------------|
| Drunk Driving Prevention Month | (202) 366-6976 |
|--|----------------|

NIPCO Formed by NARD

The National Institute for Pharmacist Care Outcomes (NIPCO) held its first meeting last month -- NIPCO was founded by NARD to support the delivery of pharmacist-directed disease management and wellness programs. NIPCO will work with national and state groups to provide accredited pharmacist care educational programming that will lead to a Pharmacist Care Diplomate status.

In conjunction with NARD Annual Convention at the beginning of October, NIPCO released the *NARD Pharmacist Care Claim Form (PCCF) User's Manual*. This manual is intended to provide pharmacists with a detail guide on how to use the new PCCF to accurately document their professional services. The manual costs \$20 for NARD members and \$30 for non-members. To order, call (800) 544-7447.

Melatonin Action Unclear

Many questions have arisen recently about melatonin, the food supplement promoted as a "natural" sleep-aid. It does not have a standard dose; recommended doses appearing on labels vary from as little as 0.3 mg to 50mg. Onset of action is said to be anywhere between 1 and 3 hours.

Melatonin's exact action is not fully understood; it appears to cause sleep by reducing core body temperature. Oral melatonin has been shown to cause rebound insomnia and next day mood changes. It affects other body systems in which biological rhythms are involved, including the menstrual cycle.

CURRENT CONCEPTS IN CARDIOLOGY

A Continuing Education Program of the Maryland Pharmacists Association

Sunday, December 3, 1995
BWI Marriott Hotel, Baltimore, Maryland



ABOUT THIS EVENT

Cardiac disease remains the number one killer of Americans. New philosophies in treating the disease present a unique challenge to pharmacists. This program is designed to provide practicing pharmacists with a comprehensive review of two major cardiac diseases -- hyperlipidemia and congestive heart failure.

REGISTRATION

This program has been made possible through an unrestricted educational grant from Merck Human Health Division. Registration is a nominal \$30 for MPhA members (\$40 for non-members). To register, complete the registration form at the bottom of this brochure. Return it to the MPhA offices no later than November 20.

LEARNING OBJECTIVES

At the conclusion of this program, the attendee will be able to:

- Describe lipid risk factors for atherosclerosis and their interaction with other risk factors.
- Relate the treatments for lipid abnormalities to prevent cerebrovascular disease.
- Identify drug-related and other causes of poor adherence in patients.
- Describe the prevalence of drug non-adherence and the effects of non-adherence on antihypertensive therapy.

PROGRAM

- | | |
|-------------------|---|
| 8:00 am | Registration and Breakfast Buffet |
| 8:30 to 9:00 am | Economic Impact of Cardiovascular Disease John F. Reitan, Pharm.D. President, Custom HealthCare Services |
| 9:00 to 10:20 am | Update on the Management of Lipid Lipid Disorders William James Howard, M.D. Vice President of Medicine Washington Hospital Center |
| 10:30 to 11:50 am | Pathophysiology and Treatment of Congestive Heart Failure Robert DiBianco, M.D. Chairman, Cardiology Department Washington Adventist Hospital |
| 11:50 to 12:30 pm | Opportunities for Pharmacists John F. Reitan, Pharm.D. President, Custom HealthCare Services |



CURRENT CONCEPTS IN CARDIOLOGY

December 3, 1995

Registration: \$30.00 for MPhA Members
\$40.00 for Non-Members

YES! Please register me for the December 3, 1995 **Current Concepts in Cardiology** seminar at the BWI Marriott Hotel. Enclosed is my payment by check or money order.

Name _____

Address _____

City/State/ZIP code _____

Complete, detach and return Registration Form to:
Cardiac CE, c/o MPhA, 650 West Lombard Street, Baltimore, Maryland 21201-1572
(410) 727-0746 (800) 833-7587 for more information

Always Double Check

Look-alike and sound-alike drug names can be misread or misinterpreted by a nurse reading doctors' orders or by a pharmacist dispensing physicians' prescriptions. Such misunderstandings can result in the administration of a drug not intended by the prescriber. Awareness of such look-alike and sound-alike drug names can reduce potential errors.

| | | |
|---------------|-------------------|----------------------|
| | <u>Achromycin</u> | <u>Adriamycin</u> |
| Category: | Antibiotic | Antineoplastic |
| Manufacturer: | Storz/Lederle | Adria |
| Generic Name: | Tetracycline | Doxorubicin |
| Dosage Form: | Capsules | Powder for Injection |

| | | |
|---------------|-----------------|----------------------------------|
| | <u>Colace</u> | <u>Calan</u> |
| Category: | Laxative | Ca ⁺⁺ Channel Blocker |
| Manufacturer: | Mead Johnson | Searle |
| Generic Name: | Docusate | Verapamil |
| Dosage Forms: | Capsules, Syrup | Tablets |

Contributed by Benjamin Teplitsky, R.Ph.

Settlement Offered

The class action lawsuits alleging antitrust violations by pharmaceutical manufacturers are proceeding towards an April 1996 court date.

Purdue-Frederick, the smallest of the defendant companies named in *Brand Name Prescription Drugs Antitrust Litigation vs. Abbott Labs, et. al.*, has offered a proposed settlement agreement to the attorneys representing the class of independent and chain pharmacies. This settlement agreement includes a one-time payment of \$1.4 million into a fund which can be used by the class action attorneys to pay to prepare and try this action against the remaining defendants next spring.

Perhaps of more importance, the settlement agreement does not include any injunctive relief from discriminatory pricing practices by Purdue-Frederick. It does not include an admission of guilt or any wrongdoing in pricing nor does it include any prohibition against future discriminatory pricing practices by that company. The proposed settlement does not include any agreement by Purdue-Frederick to be bound by any court order against the remaining defendants to cease discriminatory pricing issued either after trial or settlement of the case against the remaining defendants.

Pharmacists involved in the class action lawsuit may express their opinions on the proposed settlement by sending their written comments to: Brand Name Prescription Drug Antitrust Litigation, Post Office Box 837, Chicago, Illinois 60690-0837. All comments must be received by November 13, 1995.

Update Now

Is your Maryland Pharmacy law and regulation book up-to-date? Have you ordered your 1995 lawbook updates from MPhA?



If you didn't answer "yes" to both of those questions, you're putting yourself and your practice at risk from the biggest violation of all -- ignorance of the law!

Updates are available to MPhA members for \$12.55 (\$11.95 plus 5% Maryland tax) by calling (800) 833-7587. Non-members may purchase the updates as well for \$23.05 (\$21.95 plus 5% Maryland tax).

New Self-Care Consulting Program

APhA and USP have combined forces to provide a new self-care education initiative. The APhA/USP Assessment, Communication and Evaluation Program (ACE) is a two part course that encourages pharmacists to provide structured self-care consultations to their patients.

Part I teaches pharmacists how to perform a consultation in a formal educational session followed by a videotaping. The session will be offered during the upcoming APhA Annual Convention in Nashville, TN.

Part II consists of a national contest with one pharmacist from each state association competing to demonstrate their self-care consultation skills. State contestants will be given a case study, be given time to prepare to speak with a patient about the problem, and consult with a patient/actor while being videotaped.

If you're interested in representing Maryland and MPhA in the Part II portion of ACE, please call MPhA Executive Director Dave Miller at (410) 727-0746 for a briefing on the program.

Francis S. Balassone Memorial Lecture

The Challenge to Pharmacy from Changes in the Maryland Health Policy

Guest Speaker

Martin Wasserman, M.D., J.D., Secretary
Department of Health and Mental Hygiene

November 30, 1995, 7:30 pm
UMAB School of Pharmacy, Balassone Hall
Refreshments at 7:00 pm, dessert and coffee will follow

Post Scripts

- R Schering's "Commitment to Care" program, designed to provide Schering products to financially indigent patients without other prescription coverage, has been extended to include Eulexin 125mg. For information on patient enrollment, call the program at (800) 521-7157. Qualifying patients are eligible for assistance for up to six months.
- R FoxMeyer has launched its "FoxSource Generics Program" which provides independent pharmacies and retail buying groups with very competitive pricing on generic prescription lines. FoxSource focuses on approximately 1,500 prescription items sold by leading generic drug manufacturers.
- R Merck's Fosamax is the first treatment for osteoporosis, the bone degeneration disease that affects 20 million American women. Proper dosing and patient counseling by pharmacists is essential for the success of treatment. Doses should be taken first thing in the morning with a full-glass of plain water -- no juice or coffee, just water. Patients must wait at least 30 minutes before eating any food, drinking any beverage or taking any other medications. Patient should continue to take calcium and vitamin D if dietary intake is inadequate. An interesting caution, patient should be instructed not to lie down for at least 30 minutes after taking Fosamax.
- R CareStream Corporation has established an educational grant for their proprietary pharmaceutical care training to non-profit, professional organizations or academic institutions engaged in the promotion of pharmacy patient care. Designed by pharmacist Jeanne Ann Stasny, the program is the industry's premier pharmaceutical care model and was purchased by FoxMeyer this past May. Stasny's model is recognized nationwide as the template for the development of pharmacy services that integrate patient counseling, cognitive services, pharmacy practice management information, technology and work flow processes.
- R A recent study concluded that the use of an estrogen/androgen combination may provide enhanced symptom relief in older postmenopausal women. The study compared oral esterified estrogens with and without low-dose oral androgen (Estratab vs. Estratest). Both treatments significantly relieved physical symptoms of hot-flashes, sweating and vaginal dryness; the combined therapy provided relief from psychosomatic symptoms of fatigue, insomnia and palpitations.
- R Copley Pharmaceuticals launched mebendazole tablets in early October, the first generic equivalent to the brand Vermox. Mebendazole is used in the treatment of pinworm.



- R Abbott Laboratories is requesting FDA approval for sertindole, a new therapy for manifestations of psychotic disorders including the positive and negative symptoms of psychosis.
- R Zeneca has filed a new drug application for Accolate (zafirlukast), a leukotriene receptor antagonist for the treatment of asthma. Accolate is one of the first in a new class of medications that selectively block the effect of leukotrienes, substances that cause bronchoconstriction, inflammation, edema, and mucus secretion in the lungs.
- R Key Pharmaceuticals has launched Uni-DUR extended release theophylline tablets. Uni-DUR is a once daily dosage of theophylline indicated for the treatment of asthma and COPD.
- R Duquesne University School of Pharmacy, celebrating its 70th anniversary this year, announced in mid-September that they had received a major grant from Mylan, the nation's largest independent generic drug company. In recognition of the new relationship, Duquesne has changed the school's name to the Mylan School of Pharmacy.
- R FDA's Gastrointestinal and Nonprescription Drug Advisory Committee has recommended unanimously that a non-prescription version of the anti-ulcer drug Axid (nizatidine) be approved for OTC sale. The dose of the OTC version will be 75 mg.
- R Pennsylvania Pharmaceutical Association Executive Director Carmen DiCello was named NARD's "Independent Pharmacist of the Year" in a special ceremony held at the organization's 97th Annual Convention in Las Vegas. DiCello also owns an independent pharmacy in Pottsville, PA in addition to his services to the state organization.
- R *To Lead a Better Life*, a 17 minute GlaxoWellcome educational video for older consumers, is still available for pharmacists who provide presentations to community groups. Program materials include the video, a presenter's guide, and leave-behind brochures. To obtain the presentation kit, talk with your GlaxoWellcome representative or call (800) 546-RXTV.
- R PCS has informed MPhA that it will be recontracting with all current pharmacy providers within the next few months. The new contract will update PCS' base pharmacy agreement so that it is in line with client requirements and state regulations. A summary of current plans in which each pharmacy participates will be included on an "Enrollment Form" page sent in the mailing. At the same time contracts are being renewed, pharmacies will be able to join their new Performance Networks.



Maryland Pharmacy Event Calendar

- Nov 1 Care of the Asthmatic Patient, CE Program, GBMC Conference Center. Call (410) 828-3670.
Nov 1-2 Orthopedic Fitting School (1.5 CEU's). Call (800) 225-2023
Nov 9 MSHP Seminar, Implications of Oral Serotonin Antagonists. Call (410) 752-3318.
Nov 12 AZO Monthly Meeting, Holiday Inn Pikesville.
Nov 30 Balassone Lecture, UMAB School of Pharmacy, 7:30 pm. Call (410) 706-7650 for details.
Dec 3 Cardiology Concepts, MPhA CE Program, BWI Marriott Hotel. Call (800) 833-7587.
Dec 10 AZO Monthly Meeting, Holiday Inn Pikesville.
Dec 13-17 ACA Specialty Training Program in Respiratory Diseases. Call (703) 684-8603.
1996
Jan 14 AZO Monthly Meeting, Holiday Inn Pikesville.
Jan 15-20 NARD Health Support and Appliance School and Exam, Orlando, FL. Call (800) 544-7447.
Feb 25 MPhA Mid-Year Meeting, Loews Annapolis Hotel, Annapolis, Maryland. Call (800) 833-7587.
March 10 AZO Fritz Berman Memorial Seminar, "Diseases of the Eye." Details to follow.
June 16-19 114th Annual MPhA Convention, *Charting a New Course*, Sheraton Ocean City Resort.

Help Us Build Your Organization!

Within the next two weeks, all Maryland pharmacists who do not belong to MPhA will be receiving a special mailing inviting them to become part of their state professional organization. You can do **your part** by encouraging your co-workers and colleagues to do **their part** in helping promote and protect Maryland pharmacy. All they have to do is make the same commitment you have....

Send in their MPhA Membership Dues!

NEWSLETTER

The Maryland Pharmacists Association

650 Lombard Street

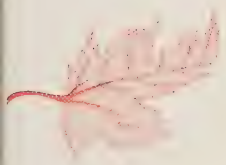
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MARYLAND PHARMACIST

October, 1995

Vol. 71, No. 10



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MARYLAND PHARMACIST

The Official Publication of The Maryland Pharmacists Association

October 1995

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They're always there when you and 30,000 others call. The Maryland Poison Center presents their annual report of poison interventions and services.

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17 Stop, Look and Listen

A "clip, post and save" for MPhA members. This USP update lists more than 200 sound-alike and look-alike drug names that can lead to medication errors.

24 Continuing Education

This month, we look at HMG CoA anti-cholesterol agents. Don't forget the CE quiz on page 30! It's free for all MPhA members and credits are now ACPE approved.

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Advertiser's Index

Whenever the opportunity arises, please thank them for their support.

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Guest Commentary

Are We Just Kidding Ourselves?

This past week I did something I haven't done in more than 15 years -- I had three prescriptions filled that I didn't dispense myself. In other words, I was a pharmacist's patient for the first time since I myself have been a pharmacist.

The prescriptions were for my wife, who is also a pharmacist, and I was in a hurry. So, like a typical consumer who chooses their pharmacy based on convenience, I figured I'd just drop in to one close to home, get the 'scrips filled, and be in and out in no time. The pharmacist there didn't know me and I didn't know her.

She took the prescriptions and asked me three questions. You've probably asked them a million times yourself. First came "How do you spell the patient's name?." Next came "What's the patient's address?" And, of course, "Do you have a prescription card?" I gave her the answers (I insisted on paying cash if only to get the personal satisfaction of making sure they made a profit on at least my prescriptions that day) and was told it would be a 45 minute wait.

Hmmm. Nobody waiting in line. No phones ringing. Why so long?

But, I know that even though a pharmacy may *look* quiet, there could be a half-dozen prescriptions waiting to be filled, physicians to be phoned, etc., etc.. So I killed some time by browsing at the bookstore and picking a few things up at the supermarket for dinner.

When I got back to the pharmacy, the prescriptions were ready. The pharmacist rang them up herself, handed me the bag, said "thanks" and walked away.

Next stop was the liquor store. I figured I'd pick up a nice bottle of wine to go with dinner. Since my total knowledge about wine can be summed up in four words -- red, white, cork, and screw-top -- I asked the proprietor what he recommended. He got up from behind the counter, came around to the wine racks, and began asking me questions. "Are you entertaining? What are you serving it with? Do you prefer a wine with a light or strong flavor?" He then proceeded to give me a brief

description of two different bottles of merlot, their various characteristics and which one he preferred (I took his recommendation, primarily because I liked the design on the label).

After paying for the wine and as I was leaving, he asked me to stop back soon and to let him know whether we liked his suggestion.

I was about half-way home when it finally hit me. I had just received more attention, more concern, and more time from a liquor store owner over my purchase of a bottle of wine than I had from the pharmacist who filled my wife's prescriptions.



David Miller, P.D.
MPhA Executive Director

The pharmacist never asked about my wife's allergies. She dispensed generics without asking or telling me they were different from what the physician had prescribed. She never told me what any of the prescriptions were for. She never bothered with those classic patient counseling quickies: "This one's an antibiotic. This one's a pain killer...." Oh, sure, I had some little leaflets stuffed into the prescription bag but they sure didn't qualify as either basic patient counseling or pharmaceutical care. I didn't expect a fifteen minute dissertation on each of those prescriptions -- that's unrealistic and next to impossible in even the least busy of community pharmacies. What I did expect was at least *some* conversation over and above "that'll be \$21.... here's your change."

We spend so much time in pharmacy talking about how pharmacists are poised to take over the responsibility as primary care providers. We make a big deal over our cultivated relationships with our patients and decry the depersonalization of pharmacy by third-parties and benefit managers who force our clientele into mail-order. We fuss over the need to be compensated for the cognitive services we provide. We think that a public relations campaign to inform the public about what we do is an absolute necessity for preserving our position within a very changing healthcare delivery system.

But all that is no more than spinning our wheels if we can't even provide the basic services to our patients that we *claim* we do on a regular basis. The pharmacist I encountered probably thinks she's doing a great job. She's not. None of us are if our sole interaction with a patient can be summed up as a piece of paper stapled to a prescription bag.

As your Executive Director, it's my responsibility to represent Maryland pharmacists and our Association throughout the state and nation. I've testified on the commitment of pharmacists to their patients, worked on programs that help improve our image to government officials, and have participated in meetings where the future of pharmacy is being

planned. No matter how frustrating and overwhelming the roadblocks have seemed toward our profession's evolution, I've always been enthusiastic and optimistic about that future.

But as I drove home from the liquor store last week, for the first time in my professional career, I seriously questioned our collective commitment to pharmacy. Frankly, we're deluding ourselves if even just one of us believe that our professional responsibility ends at making sure the right drug is given to the right patient.

That's only half our job. It's a half that technicians, machines, and mail-order can do just as well as we can. If we don't make a serious attempt to communicate with our patients now than we are doing no less than setting ourselves up for extinction.

This month is "Talk About Prescriptions Month," an annual event to promote communication between pharmacists and patients. I hope that you'll take every opportunity to have at least minimal contact with every patient who uses your practice. Use the "Prescription Checklist" on the following page as a spring-board and go from there. And try to remember, you never know if the patient across the counter is another pharmacist. MP

C.E. in the Colorado Rockies!

THE FOURTH ANNUAL WINTER CONTINUING EDUCATION AND SKI SEMINAR

Make plans early to learn in the beautiful Rocky Mountains of Colorado.

PROGRAM DESCRIPTION - The program will include 12 hours of continuing education on various subjects of interest to pharmacists of all disciplines. Continuing education topics will include: New Drugs, Achieving Win/Win Outcomes with Associates and Patients, Pharmaceutical Care/Managed Care, Aids Therapy Update, Epilepsy Drug Update, Cholesterol Drugs and the Counseling Pharmacist.

REGISTRATION: Includes 12 hours of continuing education, full breakfasts for three mornings. Limited space available. Registration for the program is \$350 per pharmacist. To reserve your spot, send registration fee or \$100 deposit (refundable through November 30, 1995) to the Colorado Pharmacists Association, 7853 E. Arapahoe Ct., Suite 1500, Englewood, CO 80112. Any questions or to receive a program schedule, call the CPhA office at (303) 843-0835.

FACULTY: Program faculty will include nationally recognized experts in their respective fields.

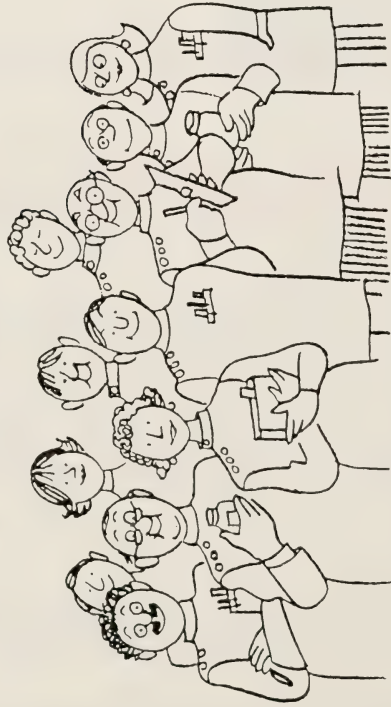
THE TIME: January 21-24, 1996

THE PLACE: BEAVER RUN RESORT - BRECKENRIDGE, COLORADO

THE DETAILS: Room prices start at \$125.00 per night (sleeps up to 4). Selection of room/suite sizes ideal for families. Beaver Run Resort phone for reservations is 1-800-525-2253. Discounted ski lift tickets available. Discounted prices on airlines and airport van to resort or rental cars through CONNIE at TRAVEL CARE, 1-800-875-3344.

Program sponsored by The Colorado Pharmacists Association

Ask Your Pharmacist!



This Rx Checklist is provided to you by your local pharmacist and the Maryland Pharmacists Association...

Good health begins with information. That's why your pharmacist wants you to know as much as possible about the prescription and over-the-counter medicines you take. Use these questions to see how much you know about your medicines.

If you don't know the answers to some of these questions...

Ask Your Pharmacist!

Rx CHECKLIST

The next time you get a prescription filled—or even if you have questions about the medication you take now—be sure to get the full story. This checklist can help. Make sure you get all the information from your pharmacist.

| | |
|--|--|
| Name of medication | _____ |
| Should I take it with food? | <input type="checkbox"/> Doesn't matter <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Can I stop the medicine when symptoms stop? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Should I use up the entire prescription? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Should I refill the prescription? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| If yes, how many times? | _____ |
| Should I see my doctor again at a particular point? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| If yes, when? | _____ |
| Is it safe to take this medication and drive a car or operate machinery? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Is it safe to go out in the sun while taking this medication? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Are there any foods I should avoid? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| If yes, which? | _____ |
| Are there any possible side effects or adverse reactions I should be aware of? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| If yes, what are they? | _____ |
| Are there any other conditions or other medications—prescription or over-the-counter—that could pose a problem with this medication? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| If yes, what are they? | _____ |
| I am currently taking the following medicines: | _____ |
| Is there any risk of addiction or tolerance (decrease in effectiveness over time) with this medicine? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| If so, how can I prevent such effects? | _____ |
| What should I do if I miss a dose? | _____ |

Ignorance of the Law...

It's No Excuse

In order to provide you with the legal information **you** need to practice in Maryland, the Maryland Pharmacists Association (MPhA) and the Maryland State Board of Pharmacy have collaborated to create a special publication entitled *Pharmacy Laws and Regulations for the State of Maryland*.



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he Maryland Poison Center (MPC) is a division of the University of Maryland School of Pharmacy and is certified by the American

Association of Poison Control Centers as a regional poison center for Maryland. In addition, the MPC serves as consultation center for the Maryland Institute for Emergency Medical Services Systems. This report presents an overview of MPC poisoning data for 1994. Additional information is available upon request. In 1994, the MPC received 57,359 calls. While 37,750 of these calls involved a human exposure, the remaining 19,609 were requests for information where no exposure had occurred.

Age

The majority of poison exposures (53.3%) involve children under the age of six.

| Age (Years) | Number | % |
|---------------|--------|------|
| <1 | 2,092 | 5.5 |
| 1 | 6,405 | 17.0 |
| 2 | 6,650 | 17.6 |
| 3 | 2,980 | 7.9 |
| 4 | 1,293 | 3.4 |
| 5 | 694 | 1.8 |
| 6-12 | 2,101 | 5.6 |
| 13-19 | 2,952 | 7.8 |
| 20-29 | 3,524 | 9.3 |
| 30-39 | 3,607 | 9.6 |
| 40-49 | 2,034 | 5.4 |
| 50-59 | 935 | 2.5 |
| 60-69 | 605 | 1.6 |
| >70 | 638 | 1.7 |
| Unknown Child | 61 | 0.1 |
| Unknown Adult | 1,112 | 2.9 |
| Unknown Age | 67 | 0.2 |

Total 37,750 100.0

Poison Exposures by Age

Serving the Public

The Annual Report of the Maryland Poison Control Center

Gender

Examination of calls for gender shows 47.9% male, 51.9% female and 0.2% unknown.

Callers

Of the calls to the MPC, (81.0%) come from the general public, (14.9%) from physicians and nurses, and (4.1%) come from emergency medical responders, pharmacists, and others. Because the Maryland Poison Center serves the entire state, statistics were maintained to identify from which county and/or metropolitan area calls to the Center were placed. These numbers appear in the chart on the following page.

Circumstances

Acute exposures account for 91.3% of the total calls, acute-on-chronic exposures account for 5.8% of calls and 2.2% are chronic exposures.

Unintentional poison exposures were tracked by the Maryland Poison Center and categorized by the type of exposure. These exposures fall into seven categories: general (23,359 exposures, 61.9%); occupational (708 exposures, 1.9%); environmental (659 exposures, 1.7%); therapeutic errors (2,158 exposures, 5.7%);

misuse (1,391 exposures, 3.7%); bites or stings (601 exposures, 1.6%); food poisonings (157 exposures, 0.4%); and unknown circumstances (45 exposures, 0.1%). In total, there were 29,078 unintentional poisoning exposures reported to the Center in 1994.

There were 6,237 intentional poisonings handled by the Center. These included poisonings by suicide attempts (4,672 exposures, 12.4% of total), misuse (826 exposures, 2.2%), abuse (350 exposures, 0.9%) and unknown intentional poisonings (389 exposures, 1.0%). Intentional poisonings accounted for 16.5% of cases handled by the Center in 1994.

In addition to general and intentional poison calls, the Maryland Poison Center also intervened in situations where poisonings occurred for other reasons. 785 exposures (2.1% of total) were due to contamination and/or tampering. 146 poisonings (0.4%) were determined to be of malicious intent. Adverse reactions to drugs, foods, and other products accounted for an additional 1,340 calls to the Maryland Poison Center.

Geographic Distribution

| County | Number | % |
|-----------------|---------------|--------------|
| Allegany | 176 | 0.5 |
| Anne Arundel | 3,687 | 9.8 |
| Baltimore | 5,270 | 14.0 |
| Baltimore City | 5,563 | 14.7 |
| Calvert | 447 | 1.2 |
| Caroline | 187 | 0.5 |
| Carroll | 1,149 | 3.0 |
| Cecil | 597 | 1.6 |
| Charles | 559 | 1.5 |
| Dorchester | 189 | 0.5 |
| Frederick | 1,022 | 2.7 |
| Garrett | 152 | 0.4 |
| Harford | 1,607 | 4.3 |
| Howard | 1,402 | 3.7 |
| Kent | 124 | 0.3 |
| Montgomery | 2,227 | 5.9 |
| Prince Georges | 1,822 | 4.8 |
| Queen Annes | 195 | 0.5 |
| Saint Marys | 603 | 1.6 |
| Somerset | 80 | 0.2 |
| Talbot | 221 | 0.6 |
| Washington | 623 | 1.6 |
| Wicomico | 399 | 1.1 |
| Worcester | 277 | 0.7 |
| Unknown | 4,126 | 10.9 |
| Maryland Total | 32,704 | 86.6 |
| Other States | 4,617 | 12.2 |
| Unknown | 407 | 1.1 |
| Other Countries | 22 | 0.1 |
| Total | 37,750 | 100.0 |

Poison Exposures by Location

Site of Exposure

Not surprisingly, the vast majority of poisonings occur at home. According to the statistics gathered, poisonings occurred at the: residence (34,347 exposures, 91.0% of total exposures); workplace (1,086 exposures, 2.9%); school (653 exposures, 1.7%); public area (370 exposures, 1.0%); health care facility (87 exposures, 0.2%); restaurant (43 exposures, 0.1%); other location (401 exposures, 2.0%); and at an unknown location (763 exposures, 2.0%).

Treatment Location

70.1 percent or 26,479 cases of poisonings were treated in non-healthcare facilities. The Maryland Poison Center referred patients to health care facilities for treatment in 9.1% or 3,418 cases. The outcome of those referrals are:

- Treated & Released (1,816)
- Admitted for Medical Care (373)
- Admitted for Psych. Care (165)
- Refused Referral (652)
- Lost to Follow-Up (412)

In 6,880 or 18.2 percent of the total interventions performed by the Maryland Poison Center, the patient exposed was already in a health care facility of some type. The results of those interventions were that the patient was:

- Treated & Released (3,629)
- Admitted for Medical Care (1,985)
- Admitted for Psych. Care (973)
- Lost to Follow-Up (293)

There were 634 cases for which no site of exposure was identified.

Route of Exposure

The vast majority of poisonings occurred from taking agents orally (30,083 cases, 73.9% of total). Other routes included: ocular (3,466 cases, 8.5%); dermal (4,390 cases, 10.8%); inhalation (1,865 cases, 4.6%); bites and stings (622 cases, 1.5%); parenteral (116 cases, 0.3%); aspiration (30 cases, 0.1%); other routes (86 cases, 0.2%). No information on the route of information was available in 57 exposures.

Medical Outcome

The medical outcome is assessed based on the inherent toxicity of the agent and the severity of the clinical manifestations. In 25,479 cases (67.5% of total), the agent was non-toxic or had no adverse health effects on the patient. Minor effects were reported in 8,264 cases (21.9%), moderate effects in 1,884 cases (5.0%), and major effects in 234 cases (0.6%). Death occurred due to the poison exposure in 37 instances (0.1%). The poison exposure had unrelated health effects in 771 cases (2.0%). The Center was unable to assess the health effects of exposure to the agent in 1,081 instances (2.9%).



Agents Involved

A single substance was involved in 90.5% of the cases. Exposures to drugs accounted for 44.4% of the calls. 41,323 agents were reported in the cases followed by the Maryland Poison Center. A breakdown of these substances, with a division between drug and non-drug agents, appears in the table at right.

Educational Programs

The MPC offers a statewide program of hospital inservices as well as presentations at grand rounds and EMS conferences. Poison center staff conducted 26 presentations in 1994. *Toxalert*, a newsletter for health professionals, offers current toxicity and treatment information on a variety of topics as well as the MPC's annual report. The MPC also acts as a training and educational site for pharmacy students and medical residents.

The MPC provides public education by a variety of mechanisms including: presentations, displays, distribution of brochures, Mr. Yuk stickers, audiovisual materials, and interaction with the media. In 1994, 11 poison prevention presentations were conducted by MPC staff.

Agents Involved in Poisonings

| Agents Involved | Number | Agents Involved | Number |
|------------------------------------|---------------|---|---------------|
| <i>Drugs</i> | | <i>Non-Drugs</i> | |
| Analgesics | 4,056 | Adhesives, Glues, Cements | 333 |
| Anesthetics | 89 | Alcohols | 1,341 |
| Anticholinergics | 104 | Arts, Crafts, Writing Products, and Office Supplies | 660 |
| Anticonvulsants | 354 | Automotive Products | 210 |
| Antidepressants | 1,362 | Batteries | 108 |
| Antihistamines | 815 | Bites & Envenomations | 649 |
| Antimicrobials | 1,093 | Building Products | 169 |
| Asthma Therapies | 381 | Chemicals | 733 |
| Cardiovascular Drugs | 704 | Cleaning Substances-Household | 4,679 |
| Cough & Cold Preparations | 2,068 | Cleaning Substances-Industrial | 126 |
| Diuretics | 105 | Cosmetics | 5,326 |
| Electrolytes/Minerals | 293 | Deodorizers | 337 |
| Eye, Ear, Nose & Throat Preps | 266 | Dyes | 54 |
| Gastrointestinal Preparations | 855 | Essential Oils | 51 |
| Hormone Products | 515 | Fertilizers | 124 |
| Muscle Relaxants | 272 | Fire Extinguishers | 46 |
| Sedative Hypnotics/Anti-Psychotics | 1,783 | Food Products & Food Poisoning | 993 |
| Stimulants/Street Drugs | 672 | Foreign Bodies | 1,315 |
| Topicals | 1,124 | Fumes, Gases, Vapors | 572 |
| Veterinary Products | 64 | Heavy Metals (excluding iron) | 115 |
| Vitamins | 930 | Herbicides | 66 |
| Miscellaneous | 292 | Hydrocarbons | 981 |
| Unknown Drugs | 172 | Insecticides | 673 |
| Total Drugs | 18,369 | Lacrimators | 369 |
| | | Matches/Fireworks/Explosives | 54 |
| | | Mothballs | 101 |
| | | Mushrooms | 126 |
| | | Paints, Varnishes, Lacquers | 389 |
| | | Plants | 1,426 |
| | | Polishes and Waxes | 173 |
| | | Rodenticides | 243 |
| | | Swimming Pool/Aquarium Products | 97 |
| | | Tobacco Products | 157 |
| | | Miscellaneous/Unknown Substances | 158 |
| | | Total Non-Drugs | 22,954 |

Acknowledgements

A special thanks to the following organizations who donated money or other valuable resources to assist with Poison Center operations and programs:

- Nationwide Insurance Company
- Baltimore Gas and Electric
- Columbia Medical Plan
- Maryland Commercial Insurance Group
- Astra Merck

Funding Update

The Maryland Poison Center (MPC) not only provides emergency poison treatment information to help save lives but also helps save money. With assistance provided via telephone, 26,479 patients were safely managed at home in 1994. By managing the appropriate patients at home, the MPC saves unnecessary ambulance dispatches and emergency department visits plus a plethora of associated emergency evaluation costs. The most

recent review of the impact of poison centers on healthcare costs demonstrated at least an eight dollar savings for every dollar spent on poison center services.

Despite the benefits provided by the MPC, funding for this service has not kept pace with our call volume. The MPC is working to find a solution to our long term funding problem. We thank those who have supported these efforts in the past and hope that with your continued support, we will secure the funding needed to provide poison center services in Maryland.

1994 Staff Members

Director

Wendy Klein-Schwartz, Pharm.D.

Assistant Director

Bruce Anderson, Pharm.D., ABAT

Medical Director

Cathleen Clancy, M.D.

Clinical Coordinator

Lisa Booze, BSPHarm, CSPI*

Specialists in Poison Information

Lisa Aukland, BSPHarm, CSPI*

Tracy Franks, BSN, R.N.

Lyn Goodrich, BSN, R.N., CSPI*

Linda Gutkoska, BSPHarm

Michael Hiotis, BSPHarm,
Janice Leonetti, BSPHarm
John Minas, BSPHarm, CSPI*
Michael Orsini, BSPHarm,
Eric Schuetz, BSPHarm, CSPI*,
Kevin Simmons, BSN, R.N., CSPI*,
Paul Starr, BSPHarm, CSPI*
Dawn Stull, Pharm.D.
Anne Tschirgi, BSPHarm, CSPI*

Administrative Aide

Annette Hurst

Maryland Green Thumb Volunteer

Goldie Henderson

Office Assistant

Darren Stokes

(*AAPCC Certified Specialist in Poison Information)

The MPC also employs health professional students to provide additional coverage for the emergency phones.

MP

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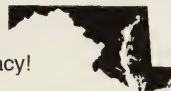


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Interactions

Pharmacy: The Next Generation

Each year we devote the entire week before classes begin in preparation for the upcoming academic year. Part of those activities is an all-day orientation for first-year students. The following excerpt is from my opening remarks to the class of 1999.

Welcome to the University of Maryland at Baltimore and to the School of Pharmacy. Your class continues the unbroken stream of over 150 generations of students educated at this University. You are an exceptional group of 100 students with an average GPA of 3.45 and PCAT scores in the 80-90 percentile. For every one of you who is sitting in the audience today, there are five applicants who have been turned away. I congratulate you on your success thus far and extend my best wishes as you progress in your career goals.

The profession of pharmacy is an integral part of the healthcare system, and our school shares this campus with our healthcare professionals in the schools of dentistry, medicine, and nursing. You will work with students from these schools during the course of your education.

Pharmacists, as health professionals, are obligated to the patients they serve. Drugs -- not as physical entities but as tools to achieve desired therapeutic outcomes in patients -- are the focal points of our interactions with those patients. Modern pharmacists, working in partnership with other health professionals, take responsibility for managing the outcomes of drug therapy in patients. This is what we call *pharmaceutical care*.

Drugs play a central role in healthcare: from curing to caring, from prevention to intervention, from the sublime alteration of a body's vital hormones to the mundane relief of a tension headache. Drugs are so common they have become an almost invisible part of the healthcare landscape, but try to imagine medicine without drug therapy! However, pharmacists know that not all drugs are benign. Modern drug therapy is increasingly complex, potent, specific, and expensive! Without careful management, drug therapy can unleash serious, unanticipated negative effects that cause enormous suffering, and drive patients into

emergency rooms and hospitals. Thus, without the context of pharmaceutical care, the major role for pharmacists is appropriate drug therapy.

Remember those words: *pharmaceutical care*. A simple concept, but a big job -- big enough to build an entire profession around! Pharmaceutical care requires active participation in all aspects of patient care, extends beyond the four walls of a pharmacy department, mandates collaboration with colleagues in the other health professions, promotes the ability to involve patients in their own care, and insists upon a covenant with patients so they will know you will always put their interests first.



**David A. Knapp, Dean
UMAB School of Pharmacy**

The program that you are entering is designed to prepare you to practice pharmaceutical care. To that end, your responsibility during the next four years is to devote yourself to developing the knowledge, skills, and abilities necessary to practice high-quality pharmaceutical care. In short, your goal is to become a premier pharmacist. To accomplish this, you must immediately take charge of your own learning. Our faculty is not here to teach you but to help you learn. This is an important distinction. I ask that you view the faculty as a group of

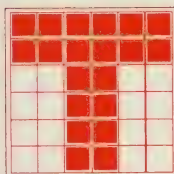
experienced coaches who share your goal of becoming an excellent pharmacist. The courses, cases, rotations, and examinations that you will encounter in the curriculum are designed to more efficiently provide you with the education you need than if you studied independently. You will need to learn quickly and efficiently how to work with your fellow students since group learning is a linchpin of our new curriculum.

I have several expectations of each of you. I expect you to: treat the needs of patients as paramount; respect and collaborate fully with your fellow students, the faculty, and colleagues in pharmacy and other health professions; be scrupulously honest in all matters. And, most importantly, maintain a full and enthusiastic commitment to your education and to the profession you have chosen to enter!

MP

Dis and Dat

Melvin Rubin, P.D., Secretary and Commissioner
Maryland State Board of Pharmacy



his month's article is a potpourri of facts and opinions, with my apologies to a certain

Baltimore sportswriter from whom I took the format.

FACT Title 10.13.07.03:-1D(1) of the Code of Maryland Regulations reads: "a prescription for a controlled dangerous substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled dangerous substances is upon the prescribing practitioner, *but a corresponding responsibility rests with the pharmacist who fills the prescriptions* (emphasis added). An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of Paragraph 285 of the Maryland Controlled Dangerous Substances Act, and the person knowingly filling such a purported prescription as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled dangerous substances."

OPINION Although the above section only relates to controlled substances, it is entirely possible that a civil suit could be brought against a pharmacist by an injured patient if the pharmacist dispensed a prescription he or she should have had reason to believe was incorrect.

Simply put, a pharmacist cannot use the excuse that the physician was called and confirmed that the medication or directions were correct. Several pharmacists have been brought before the Board recently to explain dispensing medications well in excess of approved doses. Those who have good documentation of why they felt the dose to be appropriate simply provide that evidence and the Board is satisfied. Drugs used for off-label indications or in unusual doses might need scientific justification -- professional journal articles or notations of physician documentation to the Food and Drug Administration are just two possible examples.

FACT Chapter 06 of the pharmacy regulations specify that whenever a pharmacist changes his or her primary employment location or their primary mailing address, they must notify the Board in writing of that change within 30 days. Once exception is if the pharmacist's primary employment location changes and

the pharmacists's new primary employment location is owned by the same corporation, partnership, or individual owner, the pharmacist is not required to report the change except when completing a biennial renewal form."

OPINION This serves a purpose for all of us. The Board has a better chance of locating you if needed, statistics can be developed more accurately, and most importantly, you will be more assured of receiving your application for biennial renewal. The Board is not required to do more than mail the renewal to your last known address. From that point it is up to you to be sure you renew.

FACT The Board of Pharmacy has not reviewed the entire Pharmacy Act (Title 12) for many years. Meanwhile, the profession has undergone quite a transformation. To address this problem, the Board has just begun a process designed to review the Act and revise it to reflect current and future practice.

OPINION Every pharmacist in the State should be interested in this, as should those who work in pharmacies (at this point the Board does not even use the word "technician" because it doesn't appear in our laws). While the laws will still govern dispensing, storage, etc., they will have to cover a broader area of pharmaceutical services and recognize the different requirements of each area of practice. As such, the Board will want to assure that all interested pharmacists are able to follow the proposed changes as they are formulated.

FACT The public is much more aware that pharmacists have a potential for making errors than in the past.

OPINION Just as physicians in years past relied on their bedside manner as much as their skill and knowledge, pharmacists who develop an interest in patients and find ways to let them know it, will be in a better position to know what the patient needs; this provides another checkpoint in preventing dispensing errors. If a problem does come up, the manner in which it is handled will also play a part in the way the patient reacts.

FACT The Board of Pharmacy office has undergone drastic changes in the past three years: an almost complete turnover in staff; more efficient work stations; new furniture and equipment. In addition, the offices are going to be relocated on the same floor in the Patterson Avenue building within the next year.

OPINION The increased staff, computerization, and special funding status has enabled the Board to operate much more efficiently than in the past. In particular, backlogs of disciplinary cases have been and are continuing to be reduced. The Board still moves too slowly on licensees' questions; but, even so, current problems are now being solved faster. It might take another two years, but eventually we will have rapid access to all records and the ability to analyze changing conditions among the licensees, as our increased computer capabilities and scanning equipment are installed and loaded with data.

FACT Maryland Pharmacy regulations require that a pharmacist be on duty in the pharmacy whenever someone else is in the pharmacy. Security regulations specify that only the pharmacist should have keys to the pharmacy area.

OPINION I have seen enough cases of these rules being violated to make a guess that this may be the weakest area for many pharmacies. Allowing non-pharmacists to have a key is quite a breach of security. Pharmacists are responsible for some drugs that are very attractive on the street. Several pharmacists recently have come to the attention of the Board in this area and the problem is taken very seriously.

FACT In one way or another I have written about these issues in previous articles.

OPINION The repetition is necessary because these are still problems. **MP**



Update In HIV Therapy -- 1995

A Joint Program of the Maryland AIDS Administration and the Baltimore Metropolitan Pharmacists Association

Sunday, October 29, 1995

Stouffers Inner Harbor, Baltimore, Maryland

About this Event

AIDS and HIV are patient care challenges that affect every health professional -- especially pharmacists. This special continuing education program is a joint effort of the Maryland Department of Health and Mental Hygiene AIDS Administration, the BMPA, the AIDS Education and Training Center and the UM School of Medicine to foster greater inter-professional interaction.

Registration

This program has been made possible through an unrestricted educational grant from Bristol-Myers Squibb. **There is no charge to attend**, however, you must register in advance. To register, complete the registration form at the right hand side of this brochure. Return it to the BMPA offices no later than October 25, 1995.

Learning Objectives

At the conclusion of this program, the attendee will be able to:

- State the current philosophy in the treatment of HIV and AIDS related disease.
- Explain the ideal diet for HIV patients.
- Describe specialized patient counseling techniques and services that should be made available for HIV patients.
- List common drug interactions encountered in HIV therapies.

Program

8:00 am Registration and Continental Breakfast

8:30 am to 9:40 am **An Overview of Current HIV Therapy and Management of HIV Disease**

Joel Gallant, M.D.

Director, Moore Clinic

Johns Hopkins Medical Institutions

9:50 am to 11:00 am **Nutritional Intervention in HIV Disease**

Gail Rosen, Pharm.D.

HIV Nutrition Specialist

University of Maryland Medical System

11:20 to 12:30 pm **Drug Interactions and Management of HIV Therapeutic Regimens**

James R. Minor, Pharm.D.

Clinical Center,

Department of Pharmacy

National Institutes of Health

12:30 pm Luncheon and Panel Discussion

2:00 pm Program Evaluation and Adjournment

Update in HIV Therapy - 1995

October 29, 1995

Registration: Complimentary



YES! Please register me for the October 29, 1995 **Update in HIV Therapy** seminar at the Stouffers Inner Harbor.

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HIV Update CE, c/o BMPA

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Litigation Update

Even Pharmacists Need Prescriptions

We've all been tempted -- an antibiotic here and there, maybe even a pain-killer. With easy access to medications, pharmacists may forget that we too are required to have a prescription for ourselves and our family.

The Court of Appeals of Virginia recently affirmed the conviction of a pharmacist for obtaining cephalexin and Lomotil by fraud, deceit, misrepresentation, or subterfuge. The pharmacist has been sentenced to jail and has been fined.

The facts of the case disclose that on May 6, 1991, cephalexin was validly prescribed for the pharmacist to treat a chronic sinus infection. On November 14, 1992, the pharmacist dispensed to himself a refill of the prescription, with a notation that one further refill was authorized. In fact, the pharmacist admitted at trial that this refill was not authorized by the prescriber, but that he honestly thought it would be "alright with the doctor if I updated this prescription."

Lomotil was validly prescribed to treat the pharmacist's wife's intestinal problems on March 21, 1991. On December 29, 1992, the pharmacist dispensed a refill, without authorization, using the name of the original prescriber's nurse.

After learning that the pharmacy where he worked may have discovered his actions, the pharmacist obtained additional prescriptions on January 6, 1993, from another physician for Lomotil and cephalexin, to attach to the original prescriptions. The pharmacist admitted that he secured the prescriptions from this physician to "pacify the pharmacy."

In appealing his subsequent conviction, the major issue was whether the pharmacist had acted with the requisite intent to obtain the drugs by fraud. The pharmacist testified that none of his actions was committed with the intent to defraud, misrepresent, deceive, or use subterfuge. However, the court noted that the pharmacist's obtaining the drugs was predicated on providing false

information in an attempt to comply with state law. The conviction was affirmed.

This case affirms what pharmacists already know; that a prescription is required to obtain prescription-only drugs, and that this requirement applies as much to pharmacists as it does to anyone else. Pharmacy employers and local prosecutors take this requirement seriously, and so should pharmacists. MP



David B. Brushwood, R.Ph., J.D.

Based on: *Hill v. Commonwealth*, 1995 Va.App.Lexis 557 (July 5, 1995). Copyright 1995, David Brushwood. All Rights Reserved. Reprinted from *Dickinson's Pharmacy*, August, 1995.

Stop, Look and Listen!

Avoiding Medication Errors

USP Quality Review Bulletin #49, USP Practitioners' Reporting Network

Confusion over the similarity of drug names, either when written or spoken, accounts for approximately one quarter of all reports to the USP Medication Errors Reporting Program. This naming issue involves confusion between similar brand names, generic names, and confusion between brand and generic names.

Such confusion is compounded by illegible handwriting, incomplete knowledge of drug names, newly available products, similar packaging or labeling, and incorrect selection of a similar name from a computerized product list (see Quality Review, No. 48), to name a few.

The severity of the outcome for reported incidents varies. Eight of the most severe cases resulted in a patient's death because the wrong drug was administered. In other cases, patients recognized they had received the incorrect medication before taking it and brought the error to the attention of a health care professional. In other incidents, a prescription filled with the incorrect drug was discovered by the health care professional while counseling the patient and the medication was not dispensed.

Because reporting potential medication errors is an effective preventive mechanism, conscientious health care practitioners have submitted reports on similar drug names prior to an error occurring.

Below is the list of similar drug names reported to the USP Medication Errors Reporting Program. Remember that these names may not sound alike as you read them or look alike in print, but when hand written or communicated verbally these names have caused or could cause a mix-up.

| | |
|-------------------|---------------|
| Accupril | Accutane |
| Acetohexamide | Acetazolamide |
| Adriamycin | Idamycin |
| Adriamycin | Aredia |
| Allopurinol | Apresoline |
| Altenol | Atenolol |
| Amikin | Amicar |
| Amiloride | Amlodipine |
| Amiodarone | Amrinone |
| Amoxicillin | Amoxil |
| Amoxicillin | Atarax |
| Anusol-HC | Anusol |
| Arasine | Ara-C |
| Artane | Altace |
| Asacol | Ansaid |
| Asacol | Oscal |
| Atrovent | Alupent |
| Attenuvax | Meruvax |
| Benadryl Dye-Free | Benadryl |
| Benadryl | Benylin |
| Benzac W Wash | Benzac W |
| Benylin | Ventolin |
| Betagan | Betoptic |
| Betagan | Betagen |
| Betoptic 0.5% | Betoptic S |
| Brevital | Brevibloc |

| | |
|------------------|---------------------|
| Bumex | Buprenex |
| Carboplatin | Cisplatin |
| Calcitriol | Calciferol |
| Cardene SR | Cardizem SR |
| Cardene | Cardizem |
| Cardizem CD | Cardizem SR |
| Cardura | Coumadin |
| Cefotan | Ceftin |
| Cefprozil | Cefazolin |
| Cefprozil | Cefuroxime |
| Ceftazidime | Ceftizoxime |
| Cefuroxime | Deferoxamine |
| Cefzil | Ceftin |
| Cefzil | Kefzol |
| Centoxin | Cytoxan |
| Chlorpromazine | Chlorpromamide |
| Chlorpromazine | Prochlorperazine |
| Clinoril | Clozaril |
| Clomipramine | Norpramin |
| Clomipramine | Clomiphene |
| Clonidine | Klonopin |
| Codeine | Iodine |
| Cordarone | Inocor |
| Corgard | Cognex |
| Coumadin | Compazine |
| Cyclobenzaprine | Cyproheptadine |
| Cyclophosphamide | Cyclosporine |
| Cyclosporine | Cycloserine |
| Cytovene | Cytosar |
| Cytoxan | Cytotec |
| Cytoxan | Cytosar |
| DDAVP Nasal | DDAVP W/Rhinal Tube |
| Depo-Medrol | Solu-Medrol |
| Depo-Estradiol | Depo-Testadiol |
| DiaBeta | Zebeta |
| Diazepam | Ditropan |
| Diflucan | Diprivan |
| Dilaudid | Demerol |
| Diphenatol | Diphenidol |
| Diupres | Daypro |
| Dobutrex | Diamox |
| Dolobid | Slobid |
| Dopamine | Dobutamine |
| Doxepin | Doxycycline |
| Doxorubicin | Idarubicin |
| DynaCirc | Dynacin |
| Echogen | Epogen |
| Efudex | Eurax |
| Eldepryl | Enalapril |
| Estraderm | Testoderm |
| Estratest | Estratab |
| Estratest | Eskalith |
| Ethmozine | Erythrocin |
| Etidronate | Etretnate |
| Etomidate | Etidronate |
| Fam-Pren Forte | Parafon Forte |
| Feldene | Seldane |
| Flumadine | Fludarabine |
| Fluorouracil | Flucytosine |
| Folinic Acid | Folic Acid |
| Gamimmune N | CytoGam |
| Gamulin Rh | Microgam |
| Glipizide | Glyburide |
| Glucotrol | Glyburide |
| Halprin | 1/2 Halprin |
| Hemoccult | Seracult |
| Hydrocodone | Hydrocortisone |

Hydromorphone Morphine
Hydromorphone Meperidine
Hydroxyzine Hydralazine
Imdur K-Dur
Imferon Roferon-A
Imferon Interferon
Imipenem Omnipen
Inderal La Imdur
Inderal Isordil
Inderal Adderall
Inhibace (Cilazapril in Switzerland/Japan)
. Inhibace (Captopril in Israel)
Interleukin 2 Interferon 2
K-Phos Neutral Neutra-Phos-K
Klonopin Clonidine
Lamictal Lomotil
Lanoxin Lasix
Lasix Lomotil
Leuvoxin Lanoxin
Lenoxin Lanoxin
Leucovorin Leukine
Leukine Luekeran
Levsin Levoxine
Librium Librax
Lithostat Lithobid
Lodine Iodine
Lodine Codeine
Lopid Lorabid
Lorabid Slo-Bid
Lortab Lorabid
Lortab Cortef
Lotensin Lioresal
Lotensin Loniten
Lotrimin Lotrisone
Lovastatin Lotensin
Luride Lortab
Mag. Sulfate Mag. Glucaptate
Materna Ibuprofen
Mazicon Mivacron
Medigesic Medi-Gesic
Medrol ADT Medrol Dosepak
Meproin (Atovaquone in U.S.)
. Meproin (Meprobamate in Australia)
Methylidopa L-Dopa (Levodopa)
Methylphenidate Methadone
Methylprednisolone/Medroxyprogesterone
Metolazone Methotrexate
Metoprolol Misoprostol
Micronase Micro-K
Monopril Minoxidil
Monopril Monoket
Mylanta Gas Mylicon
Narcan Norcuron
Nicoderm Nitroderm
Nifedipine Nicardipine or Nimodipine
Norflex Noroxin (Norfloxacin)
Norvasc Navane
Ocu-Mycin Ocumycin
Ocufen Ocuflox (Ofloxacin)
Ocufen Ocuress
Organidin Organidin NR
Oruvail Elavil
Paraplatin Platinol
Paroxetine Paclitaxel
Paxil Taxol
Paxil Paclitaxel
Pediapred Padiaprofen

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receive further
information,
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Medication
Errors
Reporting
Program at*

**1-800-23-ERROR
(1-800-233-7767)**

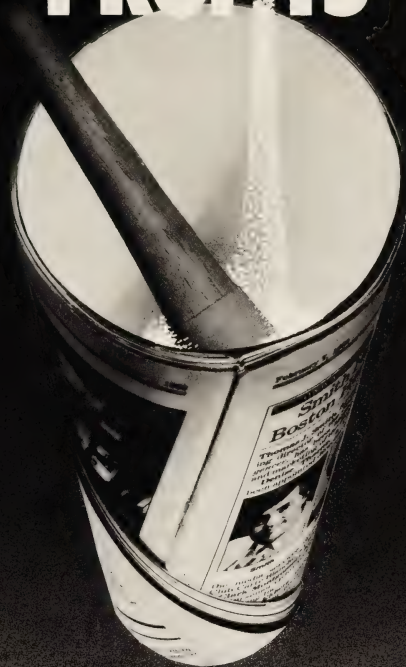
Pediaprofen Prelone
Pediaprofen Pediazole
Penicillamine Penicillin
Periactin Perative
Permax Bumex
Pindolol Parlodel
Pitocin Pitressin
Plendil Pindolol
Plendil Prinivil
Pravachol Propranolol
Prednisone Methylprednisolone
Premarin Primaxin
Prepidil Bepridil
Prilosec Prozac
Prilosec Prednisone
Prinivil Proventil
Prinivil Prilosec
Proctocream HC Proctocort
Prokine Proleukin
Proloid Prolixin
Propranolol Propulsid
Provera Premarin
Provera Provir
Prozac Proscar or Prosom
Psorion Psorcon
Quinidine Quinine
Reglan Megace
Reno-M-60 Renografin-60
Ridaura Cardura

Rifampin Rifabutin
Rimantadine Amantadine or Ranitidine
Reserpine Risperdal (Risperidone)
Roxanol Roxicet
Salagen
(Pilocarpine) name reissued in 1994
. Salagen
(Aspirin, Buffered) name retired in 1993
Sinequan Sereniti
Sodium Phosphate Potassium Phosphate
Soma Soma Compound
Stadol Haldol
Sulfasalazine Sulfisoxazole
Symmetrel Synthroid
Tegretol Toradol
Terbinafine Terfenadine
Thiamine Tenormin
Tobrex Tobradex
Toradol Inderal
Toradol Torecan
Toradol Tramadol
Torsemide Furosemide
Tridrate Trandate
Trifluoperazine Trihexyphenidyl
Tri-Norinyl Triphasil
Tussi-Organidin DM Tussi-Organidin
Vancenase Vanceril
Vantin Ventolin
Versed Vistaril
Vincristine Vinblastine
Virilon Verelan
Xanax Zantac
Yocon Zocor
Zinacef Zithromax
Zofran Zantac
Zonalon Zone A Forte
Zosyn Zofran

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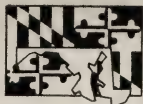
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Continuing Education

This lesson reviews HMG CoA reductase inhibitors, specifically the newest -- fluvastatin. Dosage forms and regimens are listed in Table One.

Hyperlipidemia - The Disease

Hyperlipidemia is a term that describes more than one simple disease. A number of different lipoprotein components of the diet and body function have been identified based on their density and lipoprotein content.

The most important of these are triglycerides, very low density lipoproteins (VLDL), low density lipoproteins (LDL), and high density lipoproteins (HDL). Elevations of LDL lipoprotein is a subtype of hyperlipidemia referred to as hypercholesterolemia. Elevated serum triglyceride concentration is called hypertriglyceridemia. While both of these conditions fall under the umbrella of hyperlipidemia, their treatment is different. The same is true of other forms of hyperlipidemia.

Over the years, the identification of hyperlipidemia has led to the classification of five types of the disease (Types I-V) with subclassification of Type II into IIa and IIb. These conditions differ as to which lipoprotein level(s) is or are elevated (Table Two).

New Drugs Review: HMG CoA Reductase Inhibitors

*Thomas A. Gossel, R.Ph., Ph.D., Dean
Ohio Northern University*

*J. Richard Wuest, R.Ph., Pharm.D.
Professor of Pharmacy Practice, University of Cincinnati*

A professional development program made possible by
an educational grant from **SEARLE**.

These disorders are heterogeneous groups of disorders having different pathogenic outcomes, prognoses, and responsiveness to available drugs. They are a determinant for what drugs will be used in therapy.

The focus of this lesson is the HMG CoA reductase inhibitor fluvastatin, and the types of hyperlipidemia that lead to atherosclerosis and primary coronary artery disease. These are excessive intake of cholesterol, over production or delayed catabolism of VLDL and LDL, and insufficient production of HDL.

Over the past three decades, a number of studies have been undertaken to determine whether correcting the aforementioned abnormalities is truly beneficial in reducing the progression of atherosclerotic plaque. These include the Lipid Research

Clinics -- Coronary Primary Prevention Trial (LRC-CPPT); National Heart, Lung, and Blood Institute (NHLBI); Type II Coronary Intervention Study; Cholesterol-Lowering Atherosclerosis Study (CLAS); and the Familial Atherosclerosis Treatment Study (FATS). [This is the author's favorite -- is the mnemonic appropriate or what?]

These studies have conclusively demonstrated that lowering serum VLDL and LDL levels leads to a reduction in the pathogenesis of atherosclerosis, heart attacks, development of angina, need for coronary artery bypass surgery, and death due to coronary artery disease. Recent findings are showing that accomplishing the above with the use of an HMG CoA reductase inhibitor may even provide a regression of the plaque already formed.

At this point in time, the most beneficial components of therapy for hyperlipidemia include reducing or eliminating risk factors for coronary artery disease. These are lowering elevated blood pressure, smoking cessation, weight loss, and reduced emotional stress. Therapy further includes increased exercise, reduced dietary intake of cholesterol, and use of antihyperlipidemic drugs.

Eliminating the nonreversible risk factors -- aging, heredity, and male gender -- by not getting older, choosing different parents, or undergoing a sex change might be helpful but these are obviously impractical or unattainable.

Dietary control of cholesterol and exercise are the mainstays for treating hyperlipidemia, most specifically hypercholesterolemia. Before reviewing this, it should be pointed out that cholesterol is not entirely "bad". It is essential for human life. Cholesterol is a component of animal cell walls required for the development and maintenance of myelin sheath formation in neurons. It is the building block for steroids and bile acids.

Cholesterol is so essential that the body synthesizes its own supply. On average, the liver produces 70 percent of the cholesterol needed. The rest is derived from eating animal-source food. An important factor is that at any given time, only seven percent of the total amount of cholesterol in the body is present in serum. The rest is found intracellularly, undergoing its many biochemical functions.

Problems occur when serum levels rise above this point, or there is an imbalance of the ratio of LDL to HDL levels.

Low density lipoprotein is basically responsible for carrying cholesterol from the liver to peripheral cells. High density lipoprotein carries unused cholesterol from the periphery to the liver, the gallbladder, and the intestine. When LDL levels are too high and HDL levels are too low, atherosclerosis and coronary heart disease are more likely to result.

Reduced dietary intake of cholesterol is sufficient therapy for some patients with mild cases of hypercholesterolemia. There are a number of cholesterol/fat restrictive diets that can be followed. Foremost among them are the American Heart Association (AHA) diets which basically consist of three phases of reduced cholesterol intake.

Phase I AHA diet decreases the total cholesterol from the average American intake of 400mg per day down to 300mg per day or less. Normal fat

intake is 40g per day. This diet also reduces saturated fat intake by 50 percent and increases polyunsaturated fat consumption by two- to three-fold.

Phase II AHA diet, which is recommended for moderate to severe hypercholesterolemia restricts cholesterol ingestion to 200-250mg per day with fat supplying no more than 20 percent of total calories.

Drug Therapy

When diet alone and/or a planned exercise program does not lower blood cholesterol sufficiently, several drugs are effective adjuncts. If the patient will tolerate and comply with therapy, the drugs of first choice are cholestyramine and colestipol. These drugs are bile acid sequesterant resins (BASR) which bind with bile acids in the intestine and prevent their reabsorption.

HMG CoA Reductase Inhibitors

| Generic | Brand Name | Availability | Dosage Regimen |
|-------------|------------|---------------------------|---|
| Fluvastatin | Lescol | 20 & 40 mg capsules | Initial 20mg QD hs. Maximum 40mg QD |
| Lovastatin | Mevacor | 10, 20 & 40mg tablets | Initial 20mg QD in evening. Maximum 80mg QD in the evening. |
| Pravastatin | Pravachol | 20 & 40 mg capsules | Initial 20mg QD hs. Maximum 40mg QD |
| Simvastatin | Zocor | 2.5, 5, 10 & 20mg tablets | Initial 10mg QD hs. Maximum 40mg QD |

Table One

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Hyperlipidemic Disorders

| Type | Elevated Lipoprotein | Serum Cholesterol | Serum Triglycerides | Inherited Disease | Secondary |
|------|-----------------------|-------------------|---------------------|---------------------------------|--|
| I | Chylomicrons | Normal | Elevated | Lipoprotein lipase deficiency | |
| IIa | LDL | Elevated | Normal | Familial hypercholesterolemia | Hypothyroidism, nephrotic syndrome, dietary, diabetes mellitus |
| IIb | LDL and VLDL | Elevated | Elevated | Familial mixed lipoproteinemia | |
| III | Beta-VLDL | Elevated | Elevated | Familial dysbetalipoproteinemia | Obstructive jaundice |
| IV | VLDL | Normal | Elevated | Familial triglyceridemia | Diabetes, alcoholism, dietary |
| V | Chylomicrons and VLDL | Normal | Elevated | Very rare | |

VLDL = very low density lipoproteins (high content of triglyceride)

LDL = low density lipoproteins (high content of cholesterol)

Table Two

To review, we manufacture bile acids from cholesterol in the liver and secrete them through the gallbladder into the intestine. Bile acids help emulsify lipids in the food we eat and enhance their absorption. Unused bile acids are reabsorbed from the large intestine through the enterohepatic circulation and returned to the liver for recycling.

By preventing the reabsorption of bile acids, BASR bring about an increased conversion of cholesterol into bile acids in the liver. This, in turn, lowers serum LDL cholesterol. BASR were the first antihypercholesterolemic agents to be proven to reduce the occurrence of, and death due to, coronary artery disease.

The other first-line agent is nicotinic acid. Its mechanism remains unclear, but the leading theory is that it enhances the activity of lipoprotein lipase. This decreases hepatic production of VLDL cholesterol and inhibits

breakdown of the lipids in adipose tissue.

The fibric acid derivatives (clofibrate -- Atromid S; gemfibrozil -- Lopid) also increase the activity of lipoprotein lipase, but by a different mechanism.

Another group of drugs that are effective in treating hypercholesterolemia is the HMG CoA reductase inhibitor group. These include lovastatin -- Mevacor, pravastatin -- Pravachol, simvastatin -- Zocor, and now, fluvastatin -- Lescol.

The mechanism of action of fluvastatin and other members of its group is that they inhibit hydroxy-3-methylglutaryl coenzyme A (HMC CoA) reductase. This enzyme catalyzes the early "rate limiting" step in cholesterol biosynthesis. The rate limiting notation is important because, years ago, another cholesterol inhibitor was marketed (i.e., MER-29). It led to increased morbidity because it acted at a point far along the cholesterol metabolic pathway. Over time, the precursors to cholesterol accumulated excessively leading to liver toxicity and cataract formation.

The current HMG CoA reductase inhibitors act at a point early in the metabolic pathway so the potentially toxic metabolites do not accumulate. The metabolic pathway for the synthesis of cholesterol is depicted in Figure One.

The HMG CoA reductase inhibitors reduce cholesterol synthesis in the liver which leads to increased formation of LDL receptors on peripheral cell walls. This allows for greater LDL uptake into these cells and its subsequent catabolism.

It is of interest that the names for all these drugs end in the suffix "statin". This is because the first HMG CoA reductase inhibitor, lovastatin, was obtained from a fungus -- *Aspergillus terreus*. Pravastatin and simvastatin are semi-synthetic derivatives of lovastatin.

Fluvastatin is the first totally synthetic agent in this group and its chemical formula does not resemble the others. Nonetheless, it has the same mechanism of action, and it was given the "statin" suffix like the rest. This seems to be a trend in generic name assignments as exhibited by the "olol" ending for beta-adrenergic blockers; "osin" ending for alpha-adrenergic blockers; and "pril" ending for ACE inhibitors.

While dietary measures and weight loss are key components in therapy for hypercholesterolemia, they are not sufficiently effective in a number of patients. Some people will not adhere to their diet. Similarly, while BASR and nicotinic acid are agents of first choice in treating this condition, many patients will not tolerate the side effects or comply with the dosage regimens.

Since HMG CoA reductase inhibitors are effective in treating hypercholesterolemia and cause few adverse effects, they are widely used. Many physicians believe that low dose BASR with a HMG CoA reductase inhibitor

(concurrently, but not simultaneously) is ideal therapy for hypercholesterolemia from the standpoint of both effectiveness and tolerability.

The manufacturer of Lescol has embarked on a somewhat unique marketing plan. Trying to make a significant impact on the market when the product is the fourth member of a group of presumably equally effective drugs is difficult. These agents are all taken once daily, so dosing is not a comparative edge; there is no overt difference in their side effect profiles; and they appear to be equally effective.

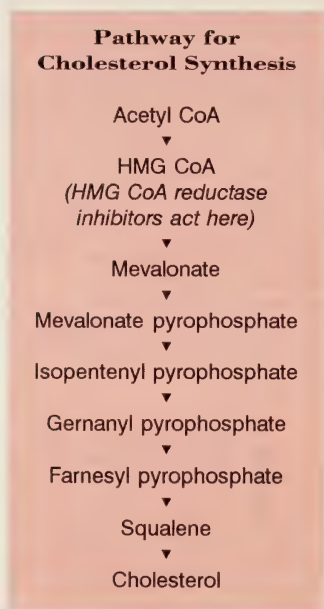


Figure One

Therefore, the manufacturer has chosen to price its product 42 to 49 percent lower than the competition. A factor in this decision is the belief that a significant number of patients, most specifically self-pay patients, discontinue taking their medication because of high cost.

The company also estimates that only 3.5 million of the potential 12.7 million patients who are candidates for HMG CoA reductase inhibitors are currently using these drugs, suggesting there is plenty of room for all four drugs in the category.

Time will tell if this strategy will be successful. At the time of preparation of this article, Lescol had not yet made the impact within the HMG CoA reductase inhibitor markets that some analysts had predicted. Others believe it is too early to tell whether the strategy will be successful. Still other industry experts have stated that the slow start is due to more competitive pricing to buying groups by the other manufacturers, and the announcement that studies have shown that lovastatin and simvastatin slow the progression of atherosclerosis and possibly cause regression. Since fluvastatin is the "new kid on the block," it will take a while for similar data to accumulate for it.

Side Effects

Adverse effects reported for fluvastatin at the five percent or higher level are: respiratory tract infections 11.6 percent (versus 15.3 percent for the placebo); headache 8.7 percent (vs 8.8); dyspepsia 8.1 percent (vs 4.9); back pain 6.1 percent (vs 8.5); diarrhea 6 percent (vs 5.6); abdominal pain 5.5 percent (vs 4.1); and influenza-like symptoms 5.3 percent (vs 5.4).

A relatively rare condition called rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with other HMG CoA reductase inhibitors. Rhabdomyolysis is a dissolution of striated muscle tissue this fatty degeneration. Myoglobinuria refers to myoglobin in urine. Myoglobin is globulin in muscle tissue. Its function is to transport oxygen in muscle. It resembles hemoglobin except that it contains only one heme moiety compared to four in the hemoglobin molecule. When myoglobin appears in urine, it is a sign of a muscle damage and/or renal failure.

The manufacturer states that this has not been seen to date with fluvastatin therapy. Myopathy has been reported in one patient on Lescol and it was related to physical exertion.

Nonetheless, patients taking fluvastatin should be advised to report to their physician promptly any unexplained muscle pain, tenderness or weakness, particularly if accompanied by tiredness or fever. Lescol therapy should be discontinued if serum CPK enzyme levels occur or myopathy is diagnosed or suspected.

Drug Interactions

The most significant interaction with some HMG CoA reductase inhibitors is seen with gemfibrozil (Lopid, etc.) leading to increased occurrence of rhabdomyolysis, explained above. There is some controversy associated with this interaction in that there are conflicting opinions as to whether it is truly significant. However, manufacturers of both types of

drugs state in their package inserts that the possible benefits of combined therapy do not outweigh the risks, and that there is no assurance that periodic monitoring of renal function will prevent the occurrence of severe myopathy or kidney damage. While this interaction has not been seen with fluvastatin, concurrently therapy is not recommended.

As can be expected, the bile acid sequestrant resins (BASR) such as cholestyramine and colestipol

bind with and antagonize the action of fluvastatin significantly by reducing its absorption, possibly as much as 80 percent, when they are taken simultaneously. However, waiting four hours between the last dose of the BASR and the bedtime dose of fluvastatin produces a clinically significant additive effect as compared to either of these drugs given alone. Therefore, combined use of a BASR and HMG CoA reductase inhibitor is considered to be good therapy. However, they should be given concomitantly but not simultaneously.

Cimetidine, ranitidine, and omeprazole reportedly cause a significant increase in the bioavailability of fluvastatin, and rifampin results in a significant decrease in its bioavailability. However, the therapeutic significance of these interactions has not been determined at this time.

Continuing Education

Goals

The goals of this lesson are to identify and discuss the actions and reactions of three new drugs introduced into therapy during 1994-95 with special emphasis given to the new drugs for the treatment of hyperlipidemia.

Objectives

At the conclusion of this lesson, successful participants should be able to:

1. exhibit knowledge of the pharmacologic classification and therapeutic considerations for fluvastatin;
2. select from a list, the indications, mechanisms of action, benefits and limitations of fluvastatin;
3. identify adverse effects, major toxicities, and drug interactions associated with fluvastatin; and,
4. demonstrate an ability to counsel patients on fluvastatin.



This program has been approved for one credit hour (0.1 CEUs) of ACPE approved continuing education. The Maryland Continuing Education Coordinating Council is an approved provider for continuing education programs for pharmacists by the American Council on Pharmaceutical Education. ACPE # 144-999-95-028-H01.

Patient Counseling Tips for Lescol

- Lescol is used to lower levels of cholesterol in the blood.
- Lescol may be taken without regard to meals. If it upsets your stomach, take it with food.
- Lescol should be taken at bedtime.
- Patients should follow the standard cholesterol lowering diet provided by their doctor while taking Lescol. Diet is the MOST important part of lowering serum cholesterol.
- It is important that Lescol be taken exactly as prescribed to maximize its effects.
- There are few side effects reported with Lescol. However, patients should inform their doctor if they experience blurred vision, muscle pain, tenderness or weakness, tiredness, fever, stomach pain, headache, nausea, skin rash, or any other bothersome or unusual side effects.

Table Three

Indications and Dosage

Like other HMG CoA reductase inhibitors, fluvastatin is indicated for use as an adjunct to diet in the treatment of elevated total cholesterol and LDL cholesterol. Its specific use is in patients with primary hypercholesterolemia (type IIa and IIb) whose response to dietary restriction of saturated fat and cholesterol and other non-pharmacologic measures have not been adequate.

The recommended dose for fluvastatin is 20mg daily, in the evening. There is no apparent difference in its lipid-lowering effect when it is taken with a meal or four hours afterward. There is a considerable difference in activity when the dose is taken in the morning, rather than at night. Morning administration is only one-half as effective compared with taking the dose at nighttime. The reason for this is that the greatest production of cholesterol in the liver occurs between 2 am and 8 am, so the nighttime dose is more effective. This is true of the other HMG CoA reductase inhibitors as well.

Additional information useful in counseling patients and caregivers on the use of Lescol is listed in Table Three.

MP

Call for Nominations

The Nominating Committee of the Maryland Pharmacists Association is seeking pharmacists who are interested in serving on the Maryland State Board of Pharmacy. Two pharmacist positions, currently occupied by Drs. Melvin Rubin and Robert Kabik, will be available.

The appointment process allows for any pharmacist in Maryland to be nominated for these positions. Any citizen of Maryland, whether a member of MPhA or not, whether a pharmacist or not, may make the actual nomination. To assure balanced practice representation on the Board, MPhA's Nominating Committee will review each nomination and select candidates qualified in the following two practice settings:



Community Chain and Institutional

To nominate a pharmacist for the Maryland State Board of Pharmacy, call the MPhA offices at (800) 833-7587 to request an official nomination form. This form must be completed and returned with the required documentation by **November 1, 1995**. No nominations submitted after this date will be considered.

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Charles E. Spigelmire, Sr. (1906-1995)

A Personal Memoir of Appreciation

Nathan I. Gruz, Executive Director Emeritus, MPhA and BMPA

A pharmacist who was irreplaceable - Charles Spigelmire - died on July 15, 1995. Here was a unique man - a "mensch," a true human being who radiated fundamental decency.

"Charlie", as he was affectionately known to his friends and colleagues, was unique in many ways.

He was the only one I knew who could not only be called upon, but volunteered, to help make the meetings and conventions of the pharmacist associations smooth running and successful. He worked not only publicly, but also behind the scenes.

In addition, Charlie was unique because he brought a demeanor of cheerfulness with him at all times. He was always "up-beat" and optimistic. He was the personification of the best of the traditional corner "Doc" in the neighborhood pharmacy which was the essential institution for primary healthcare for many generations. Charlie was also unique because he practiced the almost forgotten skills of pharmaceutical compounding until his final years.

Charlie would visit pharmacies either alone or accompanied by another pharmacist. He and I would go out together often, especially in the 1960's and 1970's, when there still were large numbers of

independent pharmacies. Sometimes these visitations were potentially hazardous. I recall visiting

pharmacies in the inner city with Charlie at the time of the assassination of Reverend Martin Luther King, Jr.. There was an ominous air in the week before the riots and the resulting burning of businesses including many pharmacies. Some pharmacists kept loaded firearms and after some visits we were escorted to our car by a clerk with a rifle.

Charlie's great talent, of course, was in securing memberships and collecting dues from delinquent members. All in pharmacy owe Charlie a great debt of gratitude for being the pre-eminent fundraiser and guardian of the treasury.

What was Charles Spigelmire's worth? The scholar Morris Joseph said it well: "The divine test of a man's worth is not his theology but his life." Charles Evans Hughes, the great Chief Justice said: "A man has to live with himself, and he should see to it that he always has good company." Charlie was always good company for all of us.

We will miss you, dear friend.

I bid him fond farewell with appreciation for his friendship and good works.

MP



Charles E. Spigelmire

Another Perspective on the Pharm.D. Degree

Lance Berkowitz, P.D., MPhA Member

Last month, the *Maryland Pharmacist* ran an article by Dean David Knapp describing the non-traditional Pharm.D. program of the University of Maryland School of Pharmacy. Having participated in the debate and discussions over whether an all-Pharm.D. program was in the best interest of pharmacy, the University and Maryland consumers, I was again angered by what I perceive to be a lack of appreciation for what pharmacy really is and where it's really going.

According to academia, the ideal pharmacist should be able to manage patients' total pharmaceutical care, from consulting with physicians, ascertaining patients' healthcare conditions, developing drug protocols and prescribing medications necessary and overseeing the dispensing of such. In the real world it "ain't" going to happen.

Why? There are three obvious reasons. For one, physicians aren't ready to give up any control on their prescribing "territory." With the pressures of managed care and exclusive networks now being felt in the medical community, physicians are finally realizing that they are seriously in danger of losing

control over the care of their patient. Are they prepared to give up more of that control to pharmacists? I doubt it. Second, more than two-thirds of pharmacists still work in a community setting (independent or chain). In a typical community setting, there is little time or consumer expectation need to provide more care than our present training already dictates. Third, many facilities that previously required a Pharm.D. trained pharmacist (hospitals, clinics and home infusion facilities) are going through re-engineering where pharmacy departments are being streamlined, downsized, and "managed" out of existence. Clearly, those facilities demand for Pharm.D. level pharmacists are declining.

On this last issue, I speak from personal experience. Just recently, I ran an ad in both the *Baltimore Sun* and the *Washington Post* for staff pharmacists with some clinical experience. Out of twenty-four applicants, eleven had Pharm.D. degrees and three were executive management pharmacists or directors at major hospitals or clinics in Pennsylvania, Maryland, Virginia, and Washington, DC. Each had their own story for applying but there was one common thread throughout. Positions for highly trained pharmacists are disappearing.

That being said, I think it's important to point out that the non-traditional Pharm.D. program at the University of Maryland isn't as wonderful as last month's article would have you believe. No mention was made that only eight of the 22 students who started in the original non-traditional Pharm.D. program will graduate when expected. And those eight only made it by taking multiple courses each semester, juggling professional and personal lives -- in other words, their success is due to their own sacrifices and perseverance, not because of the School designed a program that really meets the special needs of the practicing pharmacist.

The costs and fees for the non-traditional program are between \$8-10,000 per student. That's a substantial investment with a questionable return. Each of the 30 credit hours required for the non-traditional Pharm.D. program requires between 75-100 hours of work or approximately 2,250 - 3,000 hours in total. And, most aggravating of all, the non-traditional program was supposed to be an educational experience that a pharmacist could complete in his or her own practice. Beware though, the program now requires that everyone complete a "clinical" rotation outside of the usual practice.

If additional education for pharmacists would have a direct and positive impact on the quality of care for Marylanders, I would support both the all Pharm.D. program for undergraduates and the non-traditional track for practitioners. But when pharmacists are already well trained to provide care, I continue to question its necessity.

MP

Continuing Education Quiz

October 1995 -- Fluvastatin

This month's questions are taken from the article on fluvastatin that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. There is **no charge** for this quiz for MPhA members (non-members \$5.00). The completed quiz for this issue must be received by October 31, 1996. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE 144-999-95-028-H01.

Name _____

Address _____

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1. Which of the following is *least* likely to lead to atherosclerosis and coronary artery disease?
 - a. Excessive cholesterol intake
 - b. Over production of VLDL
 - c. Increased catabolism of LDL
 - d. Insufficient production of HDL
2. Beneficial therapy for hyperlipidemia includes all of the following components *except*:
 - a. blood pressure reduction
 - b. smoking cessation
 - c. weight loss
 - d. increased triglyceride intake
3. Which of the following statements about cholesterol is true?
 - a. Most of body cholesterol is obtained from diet.
 - b. It is an essential component for the production of steroids.
 - c. It is used to make bile salts in the gallbladder.
 - d. Most cholesterol circulates in the bloodstream.
4. Low density lipoproteins (LDL):
 - a. carry cholesterol from the liver to peripheral cells.
 - b. cause atherosclerosis when levels are too low.
 - c. cause coronary heart disease when levels are low.
 - d. carry unused cholesterol from the periphery to the liver.
5. All of the following drugs are first line therapy for hypercholesterolemia *except*:
 - a. cholestyramine
 - b. lovastatin
 - c. nicotinic acid
 - d. colestipol
6. The mechanism of action of fluvastatin involves:
 - a. prevention of the reabsorption of bile acids.
 - b. increase in the activity of lipoprotein lipase.
 - c. inhibition of coenzyme reductase.
 - d. decrease in hepatic production of VLDL cholesterol.
7. HMG CoA reductase inhibitors do all of the following *except*:
 - a. act at a point far along the cholesterol metabolic pathway.
 - b. reduce cholesterol synthesis in the liver.
 - c. increase the formation of LDL receptors on peripheral cell walls.
 - d. increase LDL uptake into peripheral cells.
8. Lescol entered the marketplace with which unique characteristic?
 - a. Once-daily dosing
 - b. Significantly lower price
 - c. Better side effects profile
 - d. Increased efficacy
9. Lescol therapy should be discontinued with increased serum levels of which of the following?
 - a. ALT
 - b. HDL
 - c. CPK
 - d. PKU
10. All of the following lower HMG CoA reductase inhibitor activity when given simultaneously *except*:
 - a. cholestyramine
 - b. colestipol
 - c. rifampin
 - d. ranitidine

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McKesson Drug Company

NEWSLETTER

The Maryland Pharmacists Association

650 Lombard Street

Baltimore, Maryland 21201

(410) 727-0746

Welcome New Members

A special "hello" to 13 new MPhA members:

| | |
|--------------------|----------------|
| Kathleen Blake | Barbara Blue |
| Henry Degeorge | Amelia Gorsuch |
| Karen Hall-Krull | Nancy Kang |
| Jason Kirby | Kyung Lee |
| Rochelle Rotenberg | William Ruth |
| Robert Stiekman | Juan Trinidad |
| John Raih | |

Technician Review Course

MSHP is offering a special pharmacy technician review course on Saturday, December 2, 1995, at the Sheppard Pratt Conference Center from 8:30 am to 4:30 pm. The review course is designed as both a refresher and a study aid to technicians planning to sit for the December Pharmacy Technician Certification Board examination.

Registration cost is \$50 and includes a copy of *Pharmacy Technician Certification -- Quick Study Guide* published by APhA. To register or obtain additional information about the course, contact MSHP at (410) 752-3318.

Board Nominations Received

Seven pharmacists have been nominated for the upcoming two Board of Pharmacy positions in 1996: Richard Baylis, David Knauer, Michael Orsini, Stanton Ades, Joseph DeMino, Wayne Dyke, and Sheldon Pelovitz. Ballots will be distributed to pharmacists in March.

November 1995

The MPhA Newsletter is published monthly except during the months of July and August when the issues are combined. For information about any article contained herein, contact MPhA at (410) 727-0746 or toll-free at (800) 833-7587. President: James Tristani, P.D.; Chairman, Board of Trustees: Arnold Davidov, P.D.; Production Manager: David Miller, P.D..

Insurance Commissioner Challenged

In an effort to preserve hard-fought protection from unfair exclusion from networks, MPhA has filed a formal suit against Maryland Insurance Commissioner Dwight Bartlett and his staff attorneys. At issue are documents withheld from MPhA's inspection under an earlier freedom-of-information act request filed by the Association in August.

The actions center around whether ex-parte discussions between the Insurance Commissioner and Blue Cross Blue Shield of Maryland compromised the Commissioner's position as an unbiased regulator of the insurance industry. Explains MPhA President **Jim Tristani**, "Blue Cross' efforts to obtain for-profit standing threatens a long-standing statute that prohibits Blue Cross from excluding pharmacies from participating in their benefit networks. If a for-profit status were to be granted, pharmacies would lose that protection."

MPhA's Board of Trustees committed resources and our corporate counsel to investigating whether the Insurance Commissioner and Blue Cross were acting in a manner consistent with state law and with good public policy. "We filed a freedom-of-information request with the Insurance Administration to gain access to all documents and records surrounding this issue in August. Imagine our surprise when, after being allowed to review the documents and order copies, the Commissioner's attorney informed us that some of the documents couldn't be copied because we should never have seen them," said MPhA's attorney Joe Kaufman. "In other words, the Insurance Commissioner wants the luxury of screening and withholding documents both before and after a freedom-of-information request."

MPhA's challenge to the handling of documents will be proceeding in the courts. In the meantime, recent press announcements have reported that Blue Cross is postponing its efforts to obtain for-profit status this year.



Drug Misuse Costs Billions



Prescription drug misuse costs the economy \$76 billion each year, not counting the lost of work place productivity. So says a new study published in the Archives of Internal Medicine. Authored by J. Lyle Bootman, Dean of the University of Arizona College of Pharmacy, the study identifies improper drug selection, subtherapeutic doses, failure to receive drugs, overdosage, adverse drug reactions, drug interactions, and use without indication as the major sources for increased financial burdens. Pharmacists, long seen as the *source* for medications, were recognized as the best source for the patient *management* of those same medications.

Experiential Learning at the School of Pharmacy

Would you like students to benefit from your experiences as a pharmacist? Would you like to offer your pharmacy as a model for students to emulate?

WE'RE LOOKING FOR A FEW GOOD MEN AND WOMEN

Due to increased number of rotations, opportunities exist for new preceptors in:

- * Drug distribution and dispensing
- * Practice and business management
- * Ambulatory clinics
- * Patient (pharmaceutical) care
- * Specialty or non-traditional practice

For further information contact:

Marvin L. Oed, B.S.P.
Coordinator, Experiential Learning
UMAB School of Pharmacy
Century Building Room 313
506 W. Fayette Street
Baltimore MD 21201
Telephone: (410)706-4192
Fax: (410)706-0897

Recent Grads... Look at This!

The American Society of Consultant Pharmacists is now accepting applications for its Executive Residency in Association Management Program. Applicants must be pharmacy graduates with good organizational and communication skills, possess an interest in association management at the state or national level, and have relevant work experience, if possible. Deadline for applications is February 1, 1996. For details, call Brandi Burkhart at (703) 739-1300.

Call for Delegates

MPhA is looking for six pharmacists who plan to attend the upcoming American Pharmaceutical Association annual convention in Nashville and who are interested in serving as delegates. President Jim Tristani, who appoints the delegates with the approval of the Board of Trustees, has asked to have as many practicing pharmacists as possible involved in the policy making process. To qualify as a delegate, you must be both an MPhA and an APhA member, be willing to attend both sessions of the APhA House of Delegates, and inform the MPhA offices of your interest no later than January 1, 1996.

Poison Workshop

The Maryland Poison Center is holding a Poison Prevention Education Workshop on Tuesday, January 9, 1996 from 10:00 am to 12:00 noon in the Brune Room of the Thurgood Marshall Law Library on the UMB campus in Baltimore.

The seminar is a kick-off to the Poison Center's annual promotion of National Poison Prevention Week, which is scheduled for March 17-23, 1996. The seminar topics include: why do poisonings occur, how they can best be prevented, and what's available to help your pharmacy plan Poison Prevention Week activities. For details, contact the Maryland Poison Center at (410) 706-7604.



Kaiser Clarifies

Last month's *Newsletter* reported that pharmacists who had outstanding claims from Kaiser Permanente should complete and send in universal claim forms. Kaiser's Accounts Payable Department says that's an unnecessary step.

In July 1995, a new Accounts Payable system was installed for the Mid-Atlantic region. The interface for transmissions from NDC has not been fully developed. This internal application has not prevented Kaiser from paying bi-weekly the NDC transmitted transactions to pharmacies. If you do have any outstanding claims, please contact Deborah Boyd at 2101 East Jefferson Street, Rockville, MD 20849 or call (301) 816-6787. Again, it is not necessary to submit a UCF to clean up your outstanding claims.

Have A Heart!

Don't forget MPhA's upcoming in-depth review of cardiovascular disease, with a special focus on congestive heart failure and hyperlipidemia. **Current Concepts in Cardiology** is scheduled for Sunday, December 3, 1995.

This four credit program will be held at the Marriott Hotel - BWI from 8:00 am to 12:00 noon. If you need some credits (especially Washington, DC licensees), call MPhA at (800) 833-7587 to reserve your space today!

Registration is only \$30 per member (\$40 per non-member). All proceeds collected go towards future educational programs planned by MPhA.



The Countdown has Started!

On December 3, 1995 Maryland Medical Assistance's new computer system MMIS-II will be up and running. That means that pharmacists will now have to enter a **nine** digit provider number for all prescribers instead of the traditional five digit number.

And if you don't use the nine digits, your claim won't be accepted, processed or paid!

To help you with the transition, MPhA has obtained a copy of the 35,000+ provider database with a complete listing of the new provider numbers. We have converted this data into a usable hard-copy book -- specifically tailored to regions of the state! We are now taking orders for the editions of our **Maryland Medicaid Provider Handbook**.

Ordering Information

Please indicate how many copies of each of the following editions of the **Maryland Medicaid Provider Handbook** you wish to order.

Central Maryland Edition

(covers Anne Arundel, Baltimore, Carroll, Cecil, Harford, and Howard counties, Baltimore City and Pennsylvania).

Western Maryland Edition

(covers Allegany, Carroll, Garrett, Frederick, and Washington counties, West Virginia and Pennsylvania)

Eastern Shore Edition

(covers Anne Arundel, Caroline, Cecil, Dorchester, Kent, Queen Annes, Somerset, Talbot, Wicomico, and Worcester counties and Delaware).

Washington Metro Edition

(covers Calvert, Charles, St. Mary's, Howard, Prince Georges, Montgomery and Frederick counties, Virginia and District of Columbia)

First Copy \$ 50 for 1995-96 MPhA Owner/Manager Category Members*
 \$ 75 for 1995-96 MPhA Members (non Owner/Manager Category)*
 \$200 for Non-Members (price includes one year's membership in MPhA)*

Subsequent \$35 each*

Copies

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Forget Something?

Recent actions by the Board of Pharmacy have focused on the failure of pharmacists and pharmacy permit holders to renew their licenses and permits. Everyone must have a valid current license in order to practice pharmacy in Maryland. If not, you and your employer may be violating the law. The following list of Maryland pharmacists who have not renewed their licenses in the past two years was provided to MPhA by the Board of Pharmacy on November 15. If you see your or a colleague's name listed, call the Board immediately at (800) 542-6964.

| | | | |
|-------------------------------|--------------------------------|-------------------------------|--------------------------------|
| Abrams, Arthur G. (93) | Carrion, Doris E. (93) | Friedman, Beverly (93) | Joo, Gregory (92) |
| Abrams, Marvin (92) | Carrion, Jose L. (93) | Frost, Gary (93) | Kantorow, Gerald (92) |
| Ackman, Joseph (93) | Cataline, Pauline M. (93) | Fruehauf, Roselin (93) | Kaplan, Samuel M. (93) |
| Adams, Gail C. (93) | Celio, Robert (92) | Galley, Roland P (93) | Kaplan, Samuel M. (93) |
| Adegoke, Mike A. (92) | Chang, Sandra S. (93) | Galloway, Howard (92) | Karn sr, Philip R (93) |
| Ajanaku, Victor (93) | Chatoff, William (93) | Garber, Neil R (93) | Katz, Susan A (93) |
| Alamdar, Seisel (92) | Chin, Yan-wing (93) | Gastonguay, Maureen M. (93) | Kaushal, Alka (93) |
| Alexander, Linnette (93) | Chivers, Curtis Brian (93) | Ghetia, Hiteshchandra M (93) | Kneip, Nasrin (92) |
| Anderson, Geraldine L (93) | Christensen, Betty R (93) | Ghoneim, Amal M. (93) | Kolasa, Tina M (93) |
| Angiolelli, Rocco J (93) | Clark, John P (93) | Gilbert, Nancy Carolyn (93) | Koons, Robert M (93) |
| Angster, Jerome (92) | Claycomb, Tricia L. (93) | Ginsberg, Bernardine (92) | Kosakowski, Chester (92) |
| Appel Sr, William J (93) | Claycomb, Tricia L. (93) | Gomez, Elaine G (93) | Koustenis, Gust (92) |
| Aronson, Donald (92) | Clifton, Cory G (93) | Grace, Dira (92) | Kramer, Jack L (93) |
| Atlas, Roy R (93) | Clinton, Mary Anne (93) | Grace, John (92) | Ku, Hanna Bonsun (93) |
| Atupulazi, Ozo M (93) | Coale, Gerard R (93) | Grant Jr, Albert B (93) | Lauer, John (93) |
| Aumeier, Helen (93) | Cohen, B Elliot (93) | Greim, Robert K (93) | Leader, Scott (92) |
| Aurora, Daljit S. (93) | Cohen, Leon L. (93) | Grove, William R (93) | Lebowitz, Cheryl J (93) |
| Ayanbiola, Edward O. (93) | Colby, Selma W (93) | Guest, Earyl (93) | Lefkowitz, Michael D. (93) |
| Bachinsky Kowal, Martha (93) | Conner, Robert C (93) | Gunza, Richard S (93) | Leggett, Gary D (93) |
| Bailey, John W (93) | Conroy Jr, Thomas M (93) | Gusakov-mason, Mary Ann (93) | Lehman, Allan (92) |
| Bainbridge, Mary Anne (93) | Cooper, Ian Scott (93) | Gyamfi, Yaw Adu-agyei (93) | Levine, Cynthia (92) |
| Baker-moses, Madeline R (93) | Cooper, Samuel (93) | Haase, Frederick R (93) | Levy, Irving (92) |
| Bankhead, Dorothy K (93) | Corder, Elizabeth (93) | Hailemeskel, Bisrat (93) | Lichter, George (93) |
| Barnes, Bertine C (93) | Corvari, Vincent (92) | Haimowitz, Linda (92) | Limoges, Theresa (92) |
| Barnett, Kathy (93) | Cox, Thomas R (93) | Hale, Barbara M. (93) | Lindenbaum, Stephen D (93) |
| Barnett, Mark (93) | Cradock, James (92) | Hansen, Jennifer (93) | Lipson, David (93) |
| Barry, Travis J. (93) | Crane, Richard (92) | Haransky, David (92) | Lovelace, Terry (93) |
| Barshack, Irwin S. (92) | Dameron, John W. (92) | Hardy, Betty (93) | Luley, Charles (92) |
| Bates, Charles L (93) | Davis, Tracy Lyn (93) | Hardy, Betty J (93) | Macek, Walter (93) |
| Baylius, Eric (93) | Davison, Robert F (93) | Hardy, Marilyn (93) | Maduka, Jason C (93) |
| Beasley, Brian (92) | Deboni II, Luigi (93) | Hare, Donald (92) | Maldonado, Davila-wanda T (93) |
| Beasley, Eula (92) | Demarest, Dudley (93) | Harnish, Robert (93) | Mark, Robert (92) |
| Beckley, John (93) | Dicanio, Patrick C (93) | Hart, Michael G. (93) | Marks, Melvyn (92) |
| Becks, Azeb (92) | Digiacinto, Valerie J. (93) | Hayes, Scott (93) | Martin, Brian P. (92) |
| Bellisario, Joan M (92) | Dinh, Caroline (92) | Headings Jr pd, L H (93) | Mascaro, Patrick Joseph (93) |
| Benchoff II, Richard (92) | Dolan, Samina B (93) | Heiser, Randy James (93) | Mask, Jerome (93) |
| Benkovic, George (93) | Dorwart, David (93) | Heisser, Trent (93) | Mauck Jr, Donald G (93) |
| Bensel, Robert (92) | Douglas, Ian M (93) | Hekimian, Berj W (93) | Mc Carty, Scott Christoph (93) |
| Berman, Mitchell (93) | Eastep, Roger (93) | Hess, Steven (93) | McCall, Donna L. (93) |
| Besser, Charles (93) | Ecklund, Douglas (93) | Highkin, Manuel (93) | McGill, Mark C. (93) |
| Binstock, Alan (93) | Edwards, Frederick W (93) | Hilliard, Susan (93) | Michael, Marvin (93) |
| Black-johnson, Felicia M (93) | Eichelberger, Bobbi (92) | Hinog, Teresita A. (92) | Miller, Harry (93) |
| Blackwell, James (93) | Eisenberg, Hannah (92) | Hinton, Cynthia (93) | Mitnick, Joel M (93) |
| Blair, Stacey Carol (93) | Elliott, Omolola (92) | Hoernle, Eliza H (93) | Monroe, Robert J (93) |
| Bockai, Sahr L (93) | Enyagberue, Andrew (93) | Hoffman, Joseph P (93) | Monti, Renard (92) |
| Bogunjoko, Grace (92) | Ervanian, Pamela (92) | Holtschneider, Douglas (93) | Morea, Christina Ann (93) |
| Bovell, Howard (92) | Esslinger, Robert (92) | Hom, Anne Conyers (93) | Morgan, Sheila R (93) |
| Brannon, Wilson (93) | Fairchild, Karen L (93) | Homonnay-Preyer, Charles (93) | Muha, Joseph (92) |
| Bregman, Robert (93) | Farah, Samia H (93) | Hontz, Cynthia (93) | Mussa, Osman A (93) |
| Breslin, Frederick W (93) | Fedder, Ira L. (93) | Hornsby, William (93) | Mutch, Richard J (93) |
| Bricker, Virginia T. (92) | Feest, Julie Marie (92) | Hruska, Lawrence G (93) | Mutchnik, Melvin (93) |
| Brigich Jr, Joseph (93) | Fink, Carolyn (93) | Huntley, Kathryn (93) | Nafziger, Karen (92) |
| Bristow-Marcalu, Suzanne (92) | Finn, William J (93) | Hurst, Clifford (92) | Nathan, Cecelia (93) |
| Brooks, Jack (93) | Finocchi, James (93) | Hvizdos, Andrew J (93) | Newell, Kathy L (93) |
| Brooks, Joe (93) | Focas, Ethel (93) | Ippolito, John (93) | Nguyen, Hoan (92) |
| Brown, Karen (92) | Foggie, Claude E (93) | Jackson Jr, Robert (93) | Nguyen, Thanh Dinh (93) |
| Brown, Stanton P (93) | Ford, Pamela Jean (93) | Jaffe, Brenda (92) | Nguyen-vo, Myhoa H (93) |
| Bryant, Joy (92) | Foster, Marthanne (92) | Jagoe, Donna Ann (92) | Nickel, Ponpun A (93) |
| Buckley, Irmgard (93) | Foulks, Deborah C (93) | Jennings, Katherine A. (93) | Njeze, Chibuzo Everist (93) |
| Bundukamara, Moses A. (92) | Fowler, Keith A (93) | John, Gerald W (93) | Northover, Edward (93) |
| Butler, Richard F (93) | Franklin, Charles E. (93) | Johnson, Clyde G. (93) | Nosal, Kimberly A (93) |
| Campbell, Thomas W (93) | Fredrickson, Marjorie Kay (93) | Johnson, Maria (93) | Nowakowski, Edmond J. (93) |
| Carl, Wendy N. (92) | | Jones, William O (93) | Ogbuchi, Sampson (92) |

Okupe, Titilola A (93)
 Osheroff, Boris J. (93)
 Osuch, Donald J (93)
 Oyekoya, Olusanya (93)
 Patel, Devendra J (93)
 Pattabiraman, Ramesh (93)
 Payne, Harry (92)
 Pepiak, Jeffrey C. (93)
 Phillips, Pamela (92)
 Pierce, Barry W (93)
 Pierson, Suzanne Janine (93)
 Pikaitis, Ann Marie (93)
 Poggi-Gabriel, Gabriel (93)
 Polakoff, Gerald H (93)
 Prasad, Vadlamani Kali (93)
 Price, Karen Ilene (92)
 Propst, Cecil W. (93)
 Ralston, Lynda (93)
 Ransom, Jacqueline Alme (93)
 Rasevisut, Nantaporn (93)
 Reaves, George (92)
 Richmond, Sewell (92)
 Riegelhaupt, Mark A (93)
 Rinde, Michael B. (92)
 Rinehart, Julie A. (93)
 Ritter, Ross W (93)
 Rogers, Debra McCoy (93)
 Ropp, David G (93)
 Rosales, Cynthia (93)
 Rosenblum, Harold (93)
 Rosser, Sheila (92)
 Ruane, Patrick Maurice (93)
 Ruane, Susan M (93)
 Saba, Christine L. (93)
 Sachs, Raymond (92)
 Saleme, Salvatore A (93)
 Salter, Susan (93)
 Sanepour, Mojgan (93)
 Santoni, Henry (92)
 Scheinin, Benjamin (93)
 Scheinker, William H. (92)
 Schneyer, Michael (93)
 Scott, Kenneth R (93)
 Segal, Ivan G (93)
 Setzler, Elisabeth A. (93)
 Shafer, Robert (93)
 Sharpe Jr, Roosevelt (92)
 Simos, Marjorie (93)
 Sindler, Melvin (92)
 Smith, Camie (93)
 Smith, Karen (92)
 Smith, Lawrence D (93)
 Smith Jr, Rudolph (92)
 Sniadowski, Anthony (93)
 Snyder, Michael P (93)
 Solomon, Henry P. (93)
 Sones, Karen (92)
 Song, Hyun (93)
 Spear Jr, Willard (93)
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 Spinelli, John A (93)
 Staska, Jerome E (93)
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 Swamy, Kumar (93)
 Tamberino, Frank J. (93)
 Tan, Jeanne (93)
 Tang, Yu-Chih (93)
 Thomas, Julie Rachel (93)
 Tiano, Susan (93)
 Torres, Carmen L (93)
 Tyler, D. Bailey (92)

Uddaraju, Sadarsana V. (93)
 Ugbo, Anthony A (93)
 Ukenye, Ann C (93)
 Urspruch, William (93)
 Valentino, James M. (93)
 Vasireddy, Vijay Kumar (93)
 Vazquez, Sarah (92)
 Venkat, Rajender (93)
 Vickers, Marcia (93)
 Vodvarka, Karen M. (93)
 Vroblesky, Barbara (92)
 Wabara, Sydney (93)
 Wade, Quartense (93)
 Waldman, Alvin (93)
 Ward, Francis (92)
 Ware II, William (93)
 Watkins, Lisa (93)
 Webster, Constance (92)
 Weiner, Bernhard (93)
 Werther, Stanford M (93)
 Wheeler, Nancy S (93)
 Wheeler III, John D. (93)
 White, Jacqueline D. (93)
 Whitesell, Reese (92)
 Whitesell, Richard J. (93)
 Wickes, Linda J (93)
 Wilson, Jacquelyn Gardn (93)
 Wisz, Richard (93)
 Wylie Jr, Hamilton (93)
 Young, Carol A. (93)
 Zanow, Nadine J. (92)
 Zaratzian, Virginia (92)
 Zeigler, Gervis (92)
 Zeiter, Roger C (93)
 Zenouzi, Emran (93)
 Zerofsky, Harold (93)
 Zervitz, Max (92)
 Zimmermann, Celine (93)

Post Scripts

- R Rhone-Poulenc Rorer has recently acquired Fisons. The integration of the two companies is expected to be completed by the first quarter of 1996. If you have questions, contact your Rhone or Fisons representative.
- R Zeneca has announced that the first phase III clinical trial results of an investigational medication called Seroquel. The product, administered at 450mg daily, significantly reduces both the positive and negative symptoms of schizophrenia. 618 patients took place in the multi-national study.
- R APhA launched a new monthly newsletter this month that will help pharmacists obtain payment for cognitive services. Entitled *Pharmacy Reimbursement and Disease Management Report* the newsletter is available for \$149 to APhA members (non-members: \$189). For subscriptions, call (800) 237-APhA.
- R 3PM computer systems now has a new tool available to help pharmacists better control their pricing. ProfitLink offers pricing data for the 200 most active drugs in your immediate area (up to 10 zip codes). It ranks drugs on: drug movement, drug refill ratio, commonly dispensed quantities, and more. For details, call (800) 521-1758.

Do You Need an RSA?

Recent Medicaid Transmittals (#21, #46) to DME suppliers has created havoc with pharmacists. The transmittal states that these supply and equipment providers must have a Residential Service Agency (RSA) license from the Department of Health and Mental Hygiene. Further, Medicaid has requested that all supply and equipment providers send this number to the Program no later than December 20, 1995.

When the RSA legislation was passed in 1994, MPhA lobbied to exempt pharmacies from having to have an RSA. After all, we argued, pharmacies already have licenses and permits and are already inspected by the Board and Division of Drug Control. Language does appear in the legislation that exempts licensed health providers who are providing service within their scope of practice from needing to get an additional license.

In addition to the statutory language, MPhA obtained clarification directly from Licensing and Certification that only "any pharmacist(s) or pharmacy(ies) which hire or contract with a second type of health care professional to provide home care service(s) will require Residential Service Agency licensure. Thus it is the employing or contracting with another health care discipline to provide home health care service which triggers the licensure requirement."

MPhA is clarifying this issue with Medicaid and the Department. As soon as the question is resolved, MPhA will notify its members.



Maryland Pharmacy Event Calendar

- Nov 30 Balassone Lecture, UMAB School of Pharmacy, 7:30 pm. Call (410) 706-7650 for details.
Dec 3 Cardiology Concepts, MPhA CE Program, BWI Marriott Hotel. Call (800) 833-7587.
Dec 10 AZO Monthly Meeting, Holiday Inn Pikesville.
Dec 13-17 ACA Specialty Training Program in Respiratory Diseases. Call (703) 684-8603.
1996
Jan 14 AZO Monthly Meeting, Holiday Inn Pikesville.
Jan 15-20 NARD Health Support and Appliance School and Exam, Orlando, FL. Call (800) 544-7447.
Feb 25 MPhA Mid-Year Meeting, Loews Annapolis Hotel, Annapolis, Maryland. Call (800) 833-7587.
March 10 AZO Fritz Berman Memorial Seminar, "Diseases of the Eye." Details to follow.
June 16-19 114th Annual MPhA Convention, *Charting a New Course*, Sheraton Ocean City Resort.

Help Us Build Your Organization!

MPhA will be mailing its second dues notice for 1996 at the beginning of December. More than 40% of members have already renewed. Have you? Help us save on postage and paper (expenses that will eat up monies that can be used in other ways) by sending in your dues payment as soon as possible. Also, don't forget to ask your colleagues whether or not they're members and, if not, tell them to....

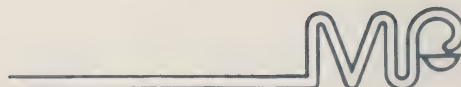
Send in their MPhA Membership Dues!

NEWSLETTER

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MARYLAND PHARMACIST

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Vol. 71, No. 11



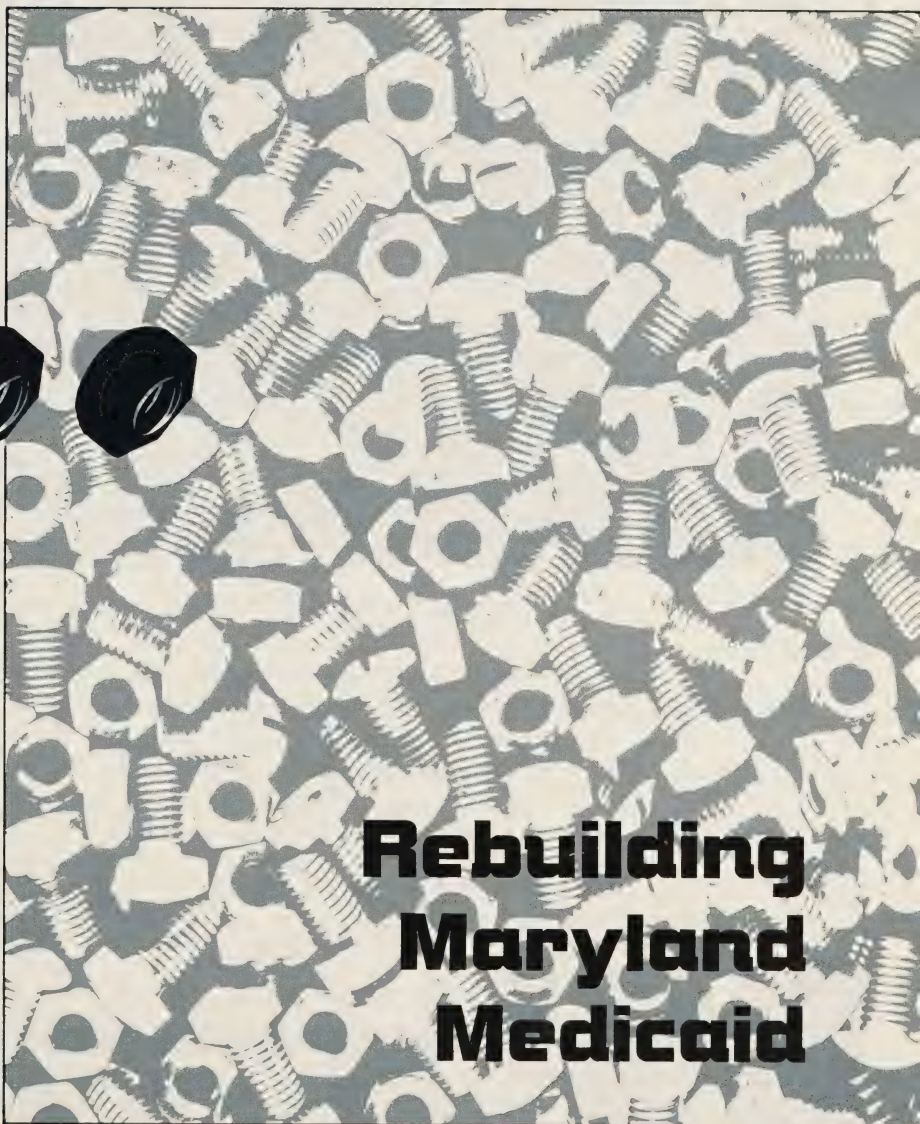
• Tooling Through
Industry

• Korean Pharmacy

• Why Doesn't the
Board...

• Interactions

• CE: Allergic
Rhinitis



Rebuilding Maryland Medicaid



Computerized Order Control

At Bergen Brunswig's Richmond Regional Distribution Center, orders are controlled and monitored by a unique computer system. The control station, pictured above, assigns a bar-coded shipping "tote" to each order. The computer is programmed with the location of every product and content of each order and routes the tote to all items requested. The result? Faster order processing with 99.9% accuracy!



Bergen Brunswig Drug Company

9900 J. E. B. Stuart Parkway • Glen Allen, VA 23060

For additional information, please call Jackie Jutchess or John Ranson at 804/553-0142 or 800/262-8470 • Fax 804/553-0144



650 West Lombard Street
Baltimore, MD 21201
(410) 727-0746

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MARYLAND PHARMACIST

The Official Publication of The Maryland Pharmacists Association

November 1995

4 President's Commentary

MPhA President Jim Tristani looks at the plans to overhaul the Maryland Medicaid System and wonders how much more pharmacists can sacrifice.

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President's Commentary

Everybody and Their Brother

James P. Tristani, MPhA President

At both its September and October meetings, the Maryland Pharmacists Association Board of Trustees were asked to develop a policy on the prescribing and/or dispensing of prescription medications by two different groups of non-physicians. Perhaps these requests, coming right behind each other, were just anomalies. However, I suspect that they are an indication of things to come.

The first group requesting MPhA's input was the local health department nurses. These nurses have been dispensing prescription drugs to health department patients for years, specifically to those who are being tracked by the tuberculosis and family planning clinics. Some of the twenty-four health departments throughout the state do contract with pharmacists to provide the dispensing services needed by these special patient populations.... most do not. Since nurses have no statutory authority to dispense medications, they wanted to introduce legislation that would give them that authority.

As originally presented, the health department nurses were looking for the ability to dispense "weekend" doses of STD therapies, contraceptives, and anti-tuberculars, for those times when the health department is closed and patients have no access to the nurses. When draft legislation was distributed for our review, those "weekend" doses had grown

to full-blown dispensing of any and all prescription drugs!

MPhA's Board took the position that pharmacists must and should be involved in providing the dispensing and pharmaceutical care services to all local health department patients. Without pharmacists, an important health benefit is potentially lost.

In October, it was the advance practice psychiatric nurses looking for prescribing and dispensing privileges. Again, the rationale for their need to prescribe and dispense was for the convenience of their patients. No thought was given to the role of pharmacists or why a pharmacist should even be involved in reviewing a prescription.

The Board resoundingly voted to protest the dispensing by either of these groups. The lack of pharmacist involvement in checking these mid-level prescri-

bers was a deciding factor.

It now seems that everybody and their brother wants to write prescriptions. While there is certainly a public policy issue in that request, I believe pharmacy's response should be quite clear: let anybody prescribe, but only let pharmacists dispense. If we're not the final check in the drug delivery system, we are doing a disservice to everybody's patients.

MP

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David G. Miller, P.D
5 October 1995

A Prescription for Managed Care

The Value of a Pharmacy Benefit "Carve Out" to Maryland Medical Assistance

*David G. Miller P.D., Executive Director
Maryland Pharmacists Association*

The pharmacists of Maryland have long recognized the need and supported efforts to properly manage our State's Medicaid prescription drug program. In fact, state and federal initiatives backed by pharmacists have resulted in two important results: better health care for Medicaid recipients and reduced cost to the State.

Maryland's Department of Health and Mental Hygiene has been working since last April to prepare a HCFA 1115 waiver application. The purpose of this application is to obtain the permission of the Health Care Finance Administration to mandatorily enroll all certain populations of Maryland Medicaid recipients into managed care organizations and/or HMOs.

Currently, a Maryland Medicaid recipient may *voluntarily* enroll in one of several area HMOs. The Department believes that placing recipients into managed care will result in substantial savings to the State.

The legislature, by enactment of Senate Bill 694, directed the Department to conduct a lengthy public process so as to ensure that all concerned had an opportunity to comment on the application. In addition to public hearings, a special Waiver Application Task Force was appointed to provide input and recommendations. MPhA Chairman Arnold Davidov represents pharmacy and pharmacists on this Task Force.

In considering where pharmacy should position itself in relation to a mandatory enrollment of patients into managed care, MPhA recognized that certain HMO models severely restrict access to pharmacists, pharmacies, and pharmaceuticals through exclusive networks and closed formularies. Those models, if used by the Department, could irreparably harm the pharmacy infrastructure in Maryland.

In addition, because of the major lawsuits between pharmacists and pharmaceutical manufacturers which are due for a court hearing in April 1996, the entire prescription purchasing and pricing system may be significantly altered. The court's decision could affect how all prescription benefits are designed and priced.

Yet, at the same time, the Association recognizes that the profession is moving towards a system where pharmacist knowledge and pharmacist services will be compensated separate from the drug product. The true savings in a pharmacy benefit comes not from discounted drug cost and lowered dispensing fees - it comes from effectively managed use and monitoring of pharmaceuticals.

For example, the expense to the health system of non-compliance has been estimated in the billions of dollars in additional medical care for treatment failure. When pharmacists intervene to control non-compliance, the entire system is saved much, much more than the nominal expense of a few additional, timely refills. Pharmacists and pharmacies must be an integral part of health systems; the value they bring to the health system must be recognized and adequately compensated.

For this and many other reasons, the Maryland Pharmacists Association took the position that the HCFA 1115 waiver application must contain a "carve out" of the prescription benefit for a period of at least two years. A "carve out" would continue the operation of the prescription benefit as currently maintained by the Medical Assistance Program regardless of whether or not a recipient enrolled in a managed

care system. We believe that our current system would sufficiently "manage" the pharmacy benefit during the time it would take to resolve the pricing and pharmacist service payment issues.

MPhA presented a formal position paper to the Waiver Application Task Force, Medicaid officials, legislators, and others. Our position paper, developed with the assistance of the Maryland Association of Chain Drug Stores, the Maryland Pharmacists Association, the Maryland Professional Pharmacies -- EPIC Pharmacy Network, and the Care Drug Centers, contends that it is in the best interest of Medicaid recipients and the Program to "carve out" the prescription benefit in any HCFA 1115 or 1915(b) Waiver Application.

Turning prescription drugs over to managed care organizations at this time is counter productive to the intent of the Omnibus Budget Reconciliation Act of 1990, a federal law whose provisions prescribe the best managed pharmaceutical care program. And the following facts bear that out.

FACT

Maryland Medicaid already has a sophisticated managed care program in place for the pharmacy benefit.

Maryland pharmacists supported federal legislation passed by Congress in 1990 (Omnibus Budget Reconciliation of 1990 or OBRA '90). This federal legislation required a substantial investment in time and money to ensure that Medicaid recipients obtain the best possible pharmacy care at the most competitive price. The provisions that all states now must use to "manage"

their prescription drug programs include:

1. online electronic claims processing;
2. prospective drug use review;
3. retrospective drug use review;
4. recognition and utilization of pharmacists' services; and
5. manufacturers' rebates to states;

The following components are necessary to a properly "managed pharmaceutical care" program, as called for in OBRA '90:

ONLINE ELECTRONIC TRANSMISSION OF CLAIMS

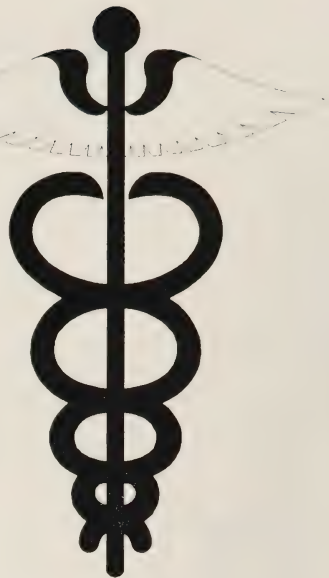
Maryland Medicaid was the first major state to go online with a fully integrated electronic processing and eligibility verification of pharmacy claims. Since our system went into operation in January 1993, many prescriptions have been rejected due to inappropriate drug therapy and fraudulent or abusive early refills. Maryland's acquisition cost of the electronic system was \$165,000 and operations for its first 10 months cost the state \$472,000.

In those same 10 months, **Maryland Medicaid saved \$6.7 million** in canceled prescriptions or denied claims.

PROSPECTIVE DRUG USE REVIEW (DUR)

Section 4401 of OBRA '90 required states to have prospective DUR established by January 1, 1993.

This DUR component calls for pharmacists to exercise their professional expertise and judge-



ment in providing quality care and clinical services, including patient counseling, to attain optimum therapeutic outcomes. Such exercises involve clinical evaluations of each prescription to identify any one or combination of the following problems before a drug is dispensed by a pharmacist:

- a. proper utilization
- b. therapeutic duplications
- c. appropriate therapeutic duration
- d. excessive daily doses
- e. insufficient daily doses
- f. evaluation of drug profiles
- g. drug-age conflicts
- h. drug-pregnancy conflicts
- i. drug-disease adverse effects
- j. drug-drug interactions and/or adverse effects
- k. drug-food interactions and/or adverse effects
- l. known allergies to medications
- m. controlled substance abuse
- n. patient compliance

The U.S. General Accounting Office (GAO) released a report of its study of the effectiveness of

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using automated systems to perform prospective DUR. The GAO concluded that significant savings are being realized, including the cancellation of over 128,000 prescriptions that posed a risk of serious adverse medical reactions.

The GAO also said prospective DUR prevents unnecessary hospitalizations and improves patient safety and quality of care through the detection of errors in prescribing and dispensing before a prescription is dispensed.

RETROSPECTIVE DRUG USE REVIEW (DUR)

OBRA '90 required states to have retrospective DUR established by January 1, 1993. Maryland, which established such a program in 1987, was used as a model to demonstrate how professional review of recipients' medical and prescription histories

can detect and prevent health problems from inappropriate medication use.

This DUR component calls for ongoing periodic review of claims data based on predetermined standards to identify patterns of inappropriate or medically unnecessary care among physicians, pharmacists, and Medicaid recipients. In addition, Maryland is one of the only states whose Retrospective DUR program is actively conducting face-to-face meetings with physicians to educate them about proper prescribing.

HMO's are not required to have any form of retrospective DUR in place for Medicaid recipients.

OBRA '90 requires states to establish a DUR Board. Data and information from retrospective DUR will be used by the

DUR Board, the entity will be responsible for educational activities, ongoing interventions, and evaluations of interventions. The objective of these activities is to educate practitioners on inappropriate prescribing and dispensing practices. Maryland's DUR Board, comprised of doctors and pharmacists, has been recognized as a national leader in developing appropriate use criteria for drug therapy.

The requirement to develop and use this valuable criteria does not extend to Medicaid recipients in HMOs.

RECOGNITION OF VALUE OF PHARMACISTS' SERVICES

OBRA '90 calls for pharmacists to counsel Medicaid patients on the proper use of prescription drugs. This is necessary to perform the prospective DUR described above. The identification



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of problems by pharmacists prior to the dispensing of medications is imperative to cost containment, appropriate drug therapy, and patient safety. Maryland's legislature enacted a revision to our Pharmacy Practice Act that requires counseling services to all Medicaid recipients.

OBRA '90 also recognized the value of pharmacists' services, expertise in drug therapy and knowledge of drug products by requiring pharmacists to serve on states' DUR Boards.

Pharmacists maintaining patient profiles, counseling patients, evaluating prescription orders, intervening, and providing other cognitive services, most of which are enumerated in prospective DUR above and required by OBRA '90, deserve compensation because such services reduce and contain cost and improve patient care.

Managed care organizations and HMOs were exempted in OBRA '90 from having to provide these types of specialized pharmacy services to Medicaid recipients.

FACT

The State benefits from substantial cost-savings in the pharmacy portion of the Maryland Medical Assistance program.

Maryland pharmacists supported federal legislation passed by Congress in 1990 (Omnibus Budget Reconciliation Act of 1990 or OBRA '90). This federal legislation requires pharmaceutical manufacturers to pay rebate monies directly to Maryland Medicaid. This law ensures that Medicaid programs pay the absolute lowest price for drugs in the marketplace.

The value of these pharmacy obtained rebate dollars is substantial. From March 1993 to December 1994, Maryland received \$38.5 million dollars in drug rebates -- \$19 million of which was used to directly offset our expenditures on Medicaid's prescription benefit.

Drug manufacturers are exempted from paying rebate money to Medicaid for any recipient who is enrolled in an HMO.

FACT

The State benefits from substantial cost-savings in the Maryland Pharmacy Assistance Program.

Maryland pharmacists worked with the Department of Health and Mental Hygiene to obtain identical drug rebate agreements for the stand-alone Pharmacy Assistance Program. From March 1993 to December 1994, that resulted in more than \$4.8 million paid back by manufacturers. All of this money is kept by Maryland to offset its Pharmacy Assistance Program.

If Medicaid moves to a managed care enrollment of all recipients, there will be little incentive for manufacturers to continue to pay rebate monies for the Pharmacy Assistance Program. Maryland will again lose millions of dollars.



FACT

There are strong public policy, access, and quality of care reasons for Maryland Medical Assistance to "carve out" its prescription drug benefit from managed care programs.

Unlike other healthcare services, these reasons are unique only to the drug program. Maryland Medicaid will lose millions of dollars in manufacturer rebates, as prescribe in OBRA '90, if the prescription drug program is provided by HMOs.

- By federal law (section 1927(j) of the Social Security Act) drugs provided by HMOs and managed care plans to Medicaid recipients are excluded from drug manufacturer rebate calculations.
- Medicaid cannot expect to recoup these rebates through lower drug prices negotiated by HMOs. While some HMOs may negotiate rebates and discounts with manufacturers, evidence does not indicate HMOs pass all these rebates and discounts along to the purchaser, which, in this case, is Maryland Medicaid.

- Restricted access to drugs, known as "formularies," are often established by HMOs to save money. These formularies are usually based on drug manufacturers' bid costs and/or the amount of rebates paid by manufacturers. Such formularies do not always contain the most "cost effective" nor all the drugs a Medicaid recipient may require.
- Segregating the 450,000 recipients from the Medicaid population among various HMOs establishes various levels of pharmaceutical care. This is contrary to Congressional intent.
- Segregating the 450,000 recipients from the Medicaid population also circumvents the centralized gathering of needed data to attain the most desired pharmaceutical care benefit program, including prospective and retrospective drug use review.
- Managing the prescription drug benefit does not mean that the State must place recipients in HMOs or managed care organizations which limit their access to pharmacies. This may impose hardships on many recipients requiring them to drive long distances for services.

Medicaid recipients' ability to change HMOs can disrupt the continuity of pharmacy care and presents serious administrative and financial problems to both the recipient and the pharmacy.

- New HMO claims administrators will not have eligibility information available in a timely manner to adjudicate claims.

- If eligibility verification cannot be attained by a pharmacist at the time of dispensing, a patient is presented the risk of not receiving needed medications.
- After changing HMOs, a recipient may not have a pharmacy immediately available for service with the new HMO.

Pharmacy services save money and reduce overall incidence of drug misuses and adverse reactions. Access to these services may be impaired under HMOs as many patients may be forced to travel long distances to fill their prescriptions. This may prove onerous to many recipients and costly to Medicaid in transportation costs.

Pharmacies are among the most accessible, cost-efficient providers of healthcare. Many Maryland pharmacies are small businesses, serving the inner cities, rural areas and other underserved populations. Our State should have an interest in preserving the already fragile community pharmacy infrastructure not only to service Medicaid recipients, but all other citizens in need of accessible pharmacy services.

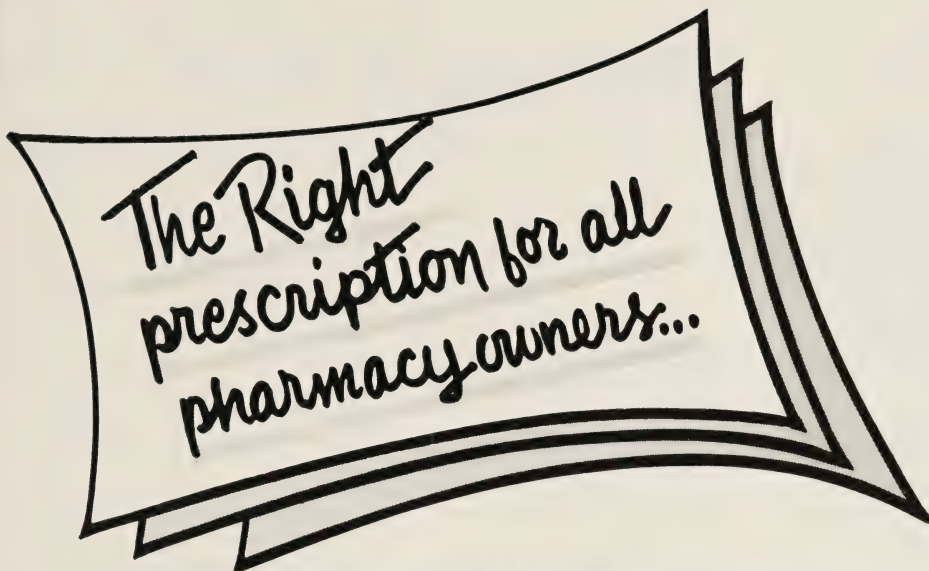
FACT

Other states are carving the prescription benefit out of their HCFA managed care waivers.

- In Texas, Governor Bush recently signed a Senate Resolution which directed the State Medicaid Agency to carve pharmacy out of the statewide waiver which it is currently drafting. Texas has already carved pharmacy out of limited managed care waiver in the Austin area.
- Delaware carved pharmacy out during the first two years of its five-year statewide managed care program.
- Nebraska carved pharmacy out of a Medicaid managed care demonstration program which just began operating. The state believes that its existing Medicaid program already effectively manages prescription care.
- Maine carved pharmacy out of Medicaid managed care demonstration project which, if approved by HCFA, will cover 2/3 of the state's Medicaid recipients.
- High-ranking Medicaid officials have indicated that pharmacy services will be carved out of statewide Medicaid managed care programs in New York and West Virginia.

In conclusion, MPhA believes that it is in the best interest of Medicaid recipients, the Medical Assistance program, and the Department of Health and Mental Hygiene to exclude the prescription drug benefit from its proposed waiver application to the Health Care Finance Administration. We have committed financial and staff resources to reach that goal.

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Pharmacy in Korea

Sarah Kang-Pak, R.Ph.



Can you imagine finding a full service pharmacy in a department store like

Macy's, at the airport, train station, or within a five minute walk from just about any home? Welcome to the Land of Morning Calm: *South Korea.*

Pharmacies are everywhere! It is not uncommon to find even two or three pharmacies on one small block. There are no chain drugstores here, only independents. The stores are small and cramped and only sell drugs with a few exceptions. There are no limitations as to the location or number of pharmacies that can be opened. However, in order to open or own a pharmacy, you must be a pharmacist.

The first pharmacy I visited was called *Dae Woo Yak Gook* which, in Chinese, translates to Big Friend Drug Store. It has been in business for 14 years in the same location. The first thing you notice when you walk into the pharmacy is the smell of Chinese medicine which consists of many herbs and sometimes animal parts. I do not know how to quite describe it except that it would be similar to walking into your neighborhood drugstore and smelling amoxicillin capsules, Dimetane syrup, and Flagyl tablets all at the same time.

The counter is low and long with a cash register at the end of it. Facing the counter about, three feet away, is a wooden bench where patients can sit down to wait; there is a small bookshelf in front of the bench stocked with various medical and drug information books for patients to read. The wall is covered by a big poster describing various skin conditions and diseases. Boxes of vitamin, ginseng, and nutrient drinks line the floors leaving just a little room for customers to walk in and out. The store hours are as follow: it opens whenever the owner decides to come in and closes at 10:00 pm on weekdays, 6:00 am on Saturdays, and it is usually closed on Sundays. These are pretty typical hours here.

At this particular pharmacy, there are three pharmacists (the owner plus two employees) and one technician. They work eight hour shifts and see about 100 patients a day. There are no printers generating labels, no counting or pouring, no telephones calls from doctors' offices. In fact, they have almost no relationship with physicians. There is not a separate filling area or counter because nothing is really filled, at least not the way we know.



A typical Korean Pharmacy. The pharmacist and owner is center, his wife and assistant is to the left and I am on the right.

So, you're probably wondering, "What do they do if not dispense?" Pharmacy is very different here. When a patient comes into the pharmacy, they speak with a pharmacist and discuss their problem. The pharmacist will ask various questions and after some counseling, the pharmacist will prescribe their medication. The medications come in prepackaged boxes that are already priced by the manufacturer. Most pharmacies, like this one, give ten percent off the manufacturers suggested retail price.

There is no charge for the counseling. Nor is there a dispensing fee. The patient can also bring in prescription from their doctor. In that case, the pharmacist hands the patients their medicine right off the shelf. The majority of patients are cash paying customers as insurance plans here will only cover compounds. At the *Dae Woo* pharmacy, a computer is used to record all purchases on insurance which they print-out once a month and send it to the government for reimbursement.

The prices are low enough that just about anyone can afford medications. For example, Tagamet costs 13 cents a tablet, Prozac and aspirin are 25 cents per pill and a 10ml vial of insulin costs \$6.00. The prices are set at local pharmacist association meetings by the store owners. The owners must discuss and vote whenever they want to raise or lower a price. In the US this would be considered price-fixing, but it is perfectly legal in South Korea. If a patient can not afford to pay for their medication, there is a government program that helps them. In this case, the patient gets a special card that they use at a hospital

Like to Travel?

If you're like most patients, it's not probably, can't visit or stay at least one pharmacist during your vacation. If you continue take some questions we'd love to hear about the similarities and differences between pharmacy here at home and abroad.

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pharmacy after they have been seen by a physician.

Everything is kept behind the counter, whether it is aspirin or morphine. Speaking of which, controlled medications are handled pretty much the same way non-controlled are except that their sale is documented. If a patient requests a controlled medication, like Percocet, the pharmacist will counsel and determine whether it is truly needed or not. In addition, the patient must be a regular customer. First time patients are required to have a prescription from the doctor. When controlled medications are sold the patient's personal information (name, address, etc...) is logged and the government does periodic audits in order to track abuse. Surprisingly, abuse is not very prevalent in Korea. There are no regulations or laws in pharmacy practice like we have in the US, except for the one about recording the sale of controlled medications.

The *Dae Woo Yak Gook* specializes in *han yak*, or Chinese medicine. There is a large metal machine near the back of the store used to make herbal juices and medicines. Boiling and steaming deer horns and various herbs for hours would not be an uncommon sight. Boiled deer horn juices are believed to give strength and good health in males, while it gives fertility and strength in females. One may also find turtle, bear, or tiger parts, and many other interesting things in Korean pharmacies. These medicines tend to be quite expensive and some people will buy the raw materials to make the medicines at home under the guidance of a pharmacist.

Han yak accounts for ten percent of this pharmacy's business. When I asked what the pharmacist would recommend for a patient, whether it would be western medicine or Chinese medicine, she responded that it would depend on the situation. However, generally she felt chronic diseases were better treated with Chinese medicine. *Han yak* is sometimes even used in place of surgery.

Pharmacists in Korea go to a university or college for four years. There is no separate pharmacy school although they major in pharmacy. Both Chinese and western medicine are taught. When they graduate, they must pass a difficult exam administered by the government in order to get their license to practice. In Korea, there are no internships or externships, and gaining experience is up to the individual. After licensing, continuing education credits are not required. As for incomes, they make above salaries comparable to American pharmacists.

I visited several other other pharmacies and found them to be similar to this one. Generally, Korean pharmacies sell medicine, hair dyes, bandages, and antiseptics although some pharmacies also sell other products such as tobacco. Medical equipment is sold separately by specialty stores. Medicines are not sold anywhere except at a pharmacy; therefore, you will not find Roloids at the local convenience store or gas station here. Fortunately, there is a pharmacy just about anywhere you look! **MP**

Some Ways to Kill an Association

- Don't come to any meetings.
- If you do come, come late.
- If the weather doesn't suit you, don't even think of coming.
- If you do attend a meeting, find fault with the work of the officers and other members.
- Never accept an office, as it is easier to criticize than to do things.
- Nevertheless, get sore if you are not appointed to a committee; but if you are, do not attend committee meetings.
- If asked by the Chairman to give your opinion regarding some important matter, tell him you have nothing to say. After the meeting tell everyone how things ought to be done.
- Do nothing more than is absolutely necessary; but when other members roll up their sleeves and willingly, unselfishly use their ability to help matters along, howl that the Association is run by a clique.
- Hold back your dues as long as possible or don't pay at all.
- Don't bother about getting new members. Let the staff do it.
- When a banquet is given, tell everybody money is being wasted on blowouts which make a big noise and accomplish nothing.
- When banquets are given say the association is dead and needs a can tied to it.
- Don't ask for a banquet ticket until all are sold. Then swear you've been cheated out of yours.
- If you do get a ticket, don't pay for it.
- If you don't receive a bill for your dues, don't pay.
- If you receive a bill after you've paid, resign from the Association.
- Don't tell the Association how it can help you; but if it doesn't help you, resign.
- If the association doesn't correct abuses in your neighbor's business, howl that nothing is done.
- If it calls attention to abuses in your own, resign from the Association.
- Keep your eyes open for something wrong and when you find it, resign.
- When you attend a meeting, vote to do something and then go home and do the opposite.
- Agree to everything said at the meeting and disagree with it outside.
- When asked for information, don't give it.
- Cuss the association for the incompleteness of its information.
- Get all the Association gives but don't give it anything.
- Talk co-operation for the other fellow with you; but never co-operate with him.
- When everything else fails, blame the other guy.

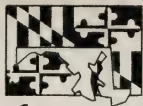
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President, UMAB Academy of Students of Pharmacy*



his summer I participated in the nine week APhA Academy of Students of Pharmacy Industry Internship

Program at Hoechst Marion Roussel, formerly Marion Merrell Dow, Inc. The internship enhanced my knowledge of the pharmaceutical industry and its role in pharmacy and medicine, as well as industry-related career opportunities. This article will share a few highlights of my internship with you. Current pharmacy students pay particular attention, for if you have any interest in the pharmaceutical industry, then you must consider participating in this enlightening and enjoyable education experience. Pharmacists and pharmacy faculty, simply peruse this article in order to better appreciate this extraordinary internship.

The last week in May, I joined three other pharmacy students from around the country to begin the internship. The first week consisted of an "Open House." The Open House week was designed to give all the interns a brief exposure to the entire company. The interns spent one-half day or a whole day with different areas of the

Company where Hoechst Marion Roussel associates described their organization and responsibilities.

Each intern ranked the available rotations from one to seven. From this, each received four two-week rotations in their areas of interest. The rotations that I was awarded were Clinical Research, Regulatory, Global Medical Information and Product Safety, and Global Professional Education/Scientific Communications. The other areas which I did not have an opportunity to rotate through were Pharmaceutical Development, Quality Control, and Sales and Marketing; although, I did spend some time in Sales and Marketing during my rotation in Professional Education.

Not only did I learn from my own experiences, but I spent a lot of time communicating with the other inters, so I was able to benefit indirectly from their experiences. The interns rotated through the departments separately, except for Clinical Research where we were paired.

The internship allowed me to match my interests and strengths with the jobs available in the pharmaceutical industry. For example, I am now very interested in Clinical Research, whereas before the internship I had no appreciation of how a pharmacist could use their skills in this area. I found the challenge of proving a drug to be safe and effective in humans both exciting and rewarding.

During my two-week rotation through Clinical Research, I wrote a practice phase III clinical protocol for an anti-AIDS drug which is now in phase II clinical trials. For this protocol, I drafted an informed consent, a case report form, and a budget. I also had the opportunity to travel with a Clinical Research Associate to two study sites. I believe I would enjoy clinical research as a career choice because it blends science with the challenges of "getting the job done."

In other words, to be successful in clinical research, I learned that a person needs to be a scientist in terms of writing protocol, interpreting and summarizing clinical data, and be able to deal with the extraordinary logistics and problems involved in running a time-conscious, cost-effective clinical study. Thus, this internship excited me about a career in pharmacy that I never knew existed. I had the opportunity to work with associates in this area to understand what skills I needed to be successful. Also, I got hands-on experience which will be useful in the future when I have to choose where I want to practice pharmacy.

While in the Global Regulatory Affairs Department, I had the opportunity to interact with a number of functional areas: U.S. Regulatory Affairs, International Drug Regulatory Affairs, Global Regulatory Chemistry Manufacturing and Controls, and Global Regulatory Compliance. During my interaction with these areas, I was exposed to a broad range of topics and activities involving good clinical practice, manufacturing practices, and laboratory practices regulations, investigational new drug and new drug applications, promotions and labeling issues, internal and FDA auditing, Freedom of Information, and DEA activities.

I witnessed the various regulatory services needed for assuring that Hoechst Marion Roussel is in conformance with all applicable government regulations in terms of the research and development, manufacturing, testing, labeling, promotion, and distribution of their drugs. I attended meetings where the regulatory associates provided guidance to other divisions of Hoechst Marion Roussel. I learned first-hand how the Regulatory Affairs Department serves as the communication link between Hoechst Marion Roussel and Regulatory Agencies (including the FDA) worldwide.

From the Regulatory rotation, I gained a strong appreciation of the intensely regulated environment in which a pharmaceutical company operates. I was surprised to learn how all aspects of the company are regulated, not just the safety and efficacy of a drug. I joked that an associate in Manufacturing could not turn a knob without prior approval from the FDA. It was a joke, but in many cases, I learned, the FDA

must be informed before, or at a least after, a change in any manufacturing process takes place. This may be obvious to some of you reading this article, but can you think of any other industry that when a knob is adjusted that it must be reported to an outside agency?

While in Global Medical Information and Product Safety, I had the opportunity to observe pharmacists handling worldwide drug information issues. I listened to medical information requests and adverse event reporting from physicians, pharmacists, nurses, and consumers. I attended meetings involving periodic safety updates

of drugs and the global labeling issues. I also was assigned several assignments that involved evaluating medical literature, summarizing medical information, and preparing written responses to inquiries. After two weeks in Medical Information and Product Safety, I have a working understanding of this area, so in the future I will be able to compare this setting to the settings in which pharmacists practice; therefore, I have a better chance of choosing a practice setting in which I will be professionally challenged and fulfilled.

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My experience in Global Professional Education/Scientific Communication is the most difficult experience to summarize, because this group is involved with such a wide variety of projects. The two primary functions of this group are to create and maintain strong relationships with the healthcare community and to communicate scientific information in support of corporate goals and for the ultimate benefit of patients. Practically speaking, the group is divided into therapeutic teams which are responsible for long-term strategic planning and development of therapeutic areas and specific products.

This group facilitates high quality, independent, CME-accredited professional education programs, while at the same time, establishing strong relationships with healthcare providers and educators within selected therapeutic areas. Additionally, the department facilitates a wide array of educational programs and support systems such as symposia, roundtables, clinical investigator meetings, intelligence gathering, video teleconferences, medical association liaison activities, and more. Professional Education associates assist Clinical Research activities by identification of potential investigators. I attended several meetings involving drugs that were in all different stages of development. For example, one meeting included a discussion of all the studies about a drug in development and brainstorming which studies needed to be published.

Also, I attended a marketing product launch meeting for a new Cardizem Injectable product that included what education programs will be offered to physicians, nurses, and pharma-

cists, pricing of the new dosage form, and the anticipated date that the product will be launched.

I also spend a day in the field with a sales representative. We called on physicians in hospitals and in their private offices. We also called on pharmacists in hospital and community pharmacies. I did not witness a formal presentation of a product which the sales representative reportedly performs two or three times a week, usually during lunch. I did however, gain an appreciation for the responsibilities of a pharmaceutical sales representative, how they interact with physicians, and the role they play in the medical community.

I think a day or more with a pharmaceutical sales representative for any pharmacy student would be helpful toward better understanding physician

prescribing habits. After all, the role of the sales representative is to educate physicians about drugs in order to increase their knowledge and influence their prescribing habits. Also many pharmacists choose sales as a career, so this was an excellent way for me to size-up this possible career choice.

During the last day of the internship, the four APhA-ASP interns met with Peter Ladell for over an hour. Peter Ladell is President of North American Commercial Operations for newly formed Hoechst Marion Roussel, now the third largest pharmaceutical company in the world. We talked about his newly acquired responsibilities and his future goals for the company. We discussed his career path, how he came to be president, key highlights of his career, and personal traits that he felt are



invaluable to succeed in today's marketplace. Mr. Ladell started his career as a sales representative, yet Fred Lyons, previous CEO of Marion Merrell Dow, Inc., began his career as a pharmacist. Therefore, from meeting with Mr. Ladell and the fact that other pharmacists were executives, I am convinced that the opportunities for a pharmacist in the pharmaceutical industry are limitless.

The flexibility of the internship at Hoechst Marion Roussel allowed me to explore the many positions in which a pharmacist can be employed. I learned that there are several

positions in the pharmaceutical industry that could potentially be a rewarding career for me. In fact, my time over the nine weeks was mostly spent talking with Hoechst Marion Roussel associates, many of whom are pharmacists. We talked about what they do, how they interact with their group, how they interact with other areas of the company and with organizations outside the company. We also talked about their personal backgrounds and what they like and dislike about their jobs. From many of the conversations, I gained valuable knowledge toward shaping my future career decisions.

Overall, I learned how Hoechst Marion Roussel is organized and the various responsibilities of different areas of the company. I interacted with many pharmacists in varied areas. I treasure my nine week industry internship and encourage students to apply in the coming years. I also urge practicing pharmacists and pharmacy faculty to support this program through encouraging pharmacy students to participate and reminding future pharmacy students of this extraordinary internship available from them. **MP**



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Why Doesn't the Board of Pharmacy....?

*Melvin Rubin, P.D., Secretary and Commissioner
Maryland State Board of Pharmacy*

I've heard those words many times during my four plus years on the Board. Often I share the frustration as much as the questioner does. So here's my compiled Top Ten (more or less) "why doesn't and why can't's" and the reasons why. Perhaps you will feel they are only rationalizations and not real answers. Either way, here goes.

....allow more leeway in the use of technicians.

For starters, the Board does not recognize technicians at this time. There is no reference to them in either law or in regulation. Of course, we know that pharmacists have ancillary personnel helping them, but our feeling is that the profession should make the decision to formally accept a group as being able to perform a specific level of competency in pharmacy. For example, the Board neither supported nor opposed the Pharm.D. degree, degrees, but recognizes it now that the profession has embraced it.

Since we consider the pharmacist responsible for the actions of *any* personnel assisting them, I expect we would have to review many laws and regulations if technicians become recognized as a group. That day may well be

fast approaching, but the profession -- not the Board -- should determine when it is upon us. Until then, and probably even afterwards, the pharmacist will still be responsible for all prescriptions and all counseling.

....stop sending in inspectors.

So, once a year you have someone breathing down your back, checking your professionalism? That's a small price to pay for the public's confidence in knowing that a well-conducted inspection showed that their pharmacy was doing everything correctly. And besides, the inspectors are under the control of the Division of Drug Control, not the Board of Pharmacy. Technicalities!

....charge lower fees for renewals.

We really are trying (does anyone find a double meaning here?). We lowered our license renewal fees last year only to find that the State was going to make us collect a new tax on each licensee to help fund the Health Care Cost and Access Commission. The Maryland Pharmacists Association, which deserves credit for keeping this tax from pharmacists for two years, is still trying to have it removed. The main rationale is that since pharmacists already work with computers capable of gathering the informa-

tion needed they should not have to pay again to provide support for developing a data collection system for other providers. If MPhA is successful, fees will go down. The Board of Pharmacy is looking at ways to lower fees anyway; but, the Board must first be sure we can fund the normal expenses, added expenses for the increased work load and new programs, and be self sufficient for the future. When the Board came under special funding it was made abundantly clear in law that we could not go to the General Fund for help.

....stop giving us more regulations.

This is a bad time to ask that question. Proposed regulations for acute care pharmacies which have been worked on almost since Cleveland won their last pennant have *finally* surfaced. The spin off regulations for long term care pharmacies, which has a pretty long history in its own right, is close to being formally proposed. Why these regulations? Because these two areas are very different than retail pharmacies and need different rules to protect the public. Are we over-regulating? Consider that the pharmacists most affected were the ones who worked on these rules with the Board. The need was almost universally accepted by your professional leadership although, naturally, there were differing opinions in different areas.

Sometimes new regulations are required by new technology. Fax machines, E-mail, electronic transfer, robotics, and those which have not been thought of yet cause the Board to make new rules.

Regulation changes are not always more restrictive. Equipment regulations and reference book rules have actually been relaxed.

.... respond to my problems and questions faster.

The Board is comprised of six pharmacists and two consumers who have to sandwich their time as Board members in between making a living at a real job. We meet once a month for a marathon session averaging almost eight hours, part of which is in a public session and with other portions pertaining to discipline in an Executive Session. The agenda for each session approaches two full pages and includes hearing from pharmacists and other professionals either on items they want to discuss or when we have requested their presence for any number of reasons. Afternoon meetings may include formal hearings (court reporter and all), informal hearings, requests to remove a suspension, or a myriad of other topics. Out of these meetings come many, many tasks to complete and many more meetings to attend.

The Board office fields literally dozens of queries a day from professionals, consumers, and the media. Many of the calls and letters require research and decision making. We try to get to everything as fast as possible and admit we sometimes have cracks for problems to fall between. Overall, I see the Board as much more responsive now than in past years. One example of that is the Board's commitment to shift much of its business to the public portions of its monthly meetings. Want to be a part of the discussion at those meetings? Show up at 8:30 am on the third Wednesday of most months.

.... leave me alone when it receives an unfounded or silly complaint.

How do we know it is unfounded or silly until we investigate? Should we handle the complaint without hearing your side of the story? We are required to investigate and answer each complaint made by a consumer and that can be as many as eight to ten in a single week. Unless the complaint is very serious -- such as a pharmacist working under the influence or without a license -- we start the ball rolling by asking the pharmacist to tell us their version. If the complaint is about an error, we ask the pharmacist to let us know what steps they are taking to attempt to insure that the error will not happen again. Sometimes this is all it takes to satisfy the Board and we inform the consumer of this by letter and close the case. However, every pharmacist must understand that any complaint becomes a part of their file and it may be reviewed again if another problem occurs.

....stop price discrimination.

We'd love to. However, that's not within the scope of the Board of Pharmacy. I could easily make a case that price discrimination is not in the best interest of the public which we are sworn to protect, but the Board does not get involved in economic issues. Sorry.

....third-parties treatment of pharmacists.

As far as the economic impacts of third-parties, the answer to this question is the same as the one I just gave. And, the anti-trust concerns of practicing pharmacists apply to the members of the Board of Pharmacy as well. Each pharmacist must decide for

themselves what they want to or can do about fees on an individual basis and act as an individual. The Board, however, would consider becoming involved when pharmacists feel that an insurance company is requiring them to do something illegal. In those instances, the Board would need to examine the activities of the third-party on a case-by-case basis.

.... examine the workload of the pharmacists.

Now here is a controversial topic. My own opinion is that pharmacists vary so much in their ability to handle a workload that we could not possibly consider looking at this issue from a numbers standpoint. We have, however, told many pharmacies to examine their own situation to set in place whatever systems or changes are needed to bring error rates down to zero. If that requires more personnel or less congestion, or whatever it takes -- do it. If the profession wants to examine this question themselves the Board can serve as a reference source and offer suggestions.

....give every pharmacist enough money to retire on.

I'm working on that one (of course, the Class of 1955 will get the first of any benefits).

Perhaps I could write a companion article of what the Board can and does do. If you think that would be a short paragraph you are wrong. The only problem would be that it wouldn't fit into this journal. **MP**

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Allergic Rhinitis Part I -- The Disease

*Thomas A. Gossel, R.Ph., Ph.D., Dean
Ohio Northern University*

*J. Richard Wuest, R.Ph., Pharm.D.
Professor of Pharmacy Practice, University of Cincinnati*

A professional development program made possible by
an educational grant from **SEARLE**.

Allergic rhinitis affects an estimated 50 or more million Americans. To many of them, mid- to late-summer brings on their greatest discomfort. Although not life-threatening, each year suffers spend more than \$300 million for medications and another \$200 million for physician services, and lose a reported 3.5 million work-days. Rhinitis (inflammation of the nasal mucosa) is the most common allergic condition treated by physicians in the US. Allergic rhinitis is the most recognizable example of allergic disease.

The vast number and variety of OTC and Rx products that contain antihistamines and/or decongestants confirm their widespread popularity. Intra nasal corticosteroid and cromolyn sodium products are also widely used to treat allergic rhinitis.

Allergic Rhinitis

The term allergic rhinitis implies the existence of a hypersensitivity response to foreign allergens mediated by IgE antibodies (explained later). Susceptibility to seasonal allergens often begins in childhood or young adulthood, being uncommon before the age of three years. Ten percent of all children and up to 30 percent of adolescents are reportedly symptomatic. Symptoms peak in post-adolescent teenagers and diminish with aging, although complete remission is uncommon. Allergic rhinitis is more prevalent

in atopic individuals. That is, it appears in persons with a family history similar or related symptom complex and a personal history of concurrent allergy expressed as eczematous dermatitis, urticaria, and/or asthma.

Allergic rhinitis is classified as seasonal (acute) or perennial (chronic). Perennial rhinitis is characterized by symptomatology throughout the year. It is provoked by factors (Table One) other than plant (airborne) allergens, such as shedding skin (epithelium) in animal and/or insect dander, processed materials or industrial chemicals, mold spores that are not linked to the changing seasons, and house dust. Dust contains a diverse content of allergens including mites. In fact, some patients with perennial rhinitis are sensitive only to house dust. For other patients with perennial rhinitis, no clear-cut allergen can be demonstrated. Patients with perennial rhinitis usually develop the problem in

adult life, and more women than men are affected. Table Two contains a classic summary of various subtypes of chronic rhinitis.

Seasonal outbreaks are cyclic and predictable, correlating with pollination patterns of offending airborne allergens. The incidence of seasonal rhinitis is approximately 10 times greater than that of perennial rhinitis. The ability of the allergens to cause rhinitis, rather than pulmonary symptoms, is attributed to their large diameter (10 to 100 micrometers). They are retained in the nose and rarely pass on to the lungs. The concentration of airborne pollens may reach up to several thousand particles/M³ on a dry, windy day.

Seasonal allergic rhinitis (pollinosis) is inappropriately referred to as *hay fever*. This term is incorrect because hay is neither a cause, nor fever a symptom! It is also referred to as *summer cold*. This designation is

inaccurate because a chemical antigen, rather than a respiratory viral infection, is at fault.

The three defined allergy seasons in the US are spring (trees), late spring/early summer (grasses), and late summer to the first frost (weeds) in autumn. The exact timing of onset of symptoms depends on the geographic location and weather, especially with respect to temperature and moisture. It varies little from year to year within a particular locale, but may be significantly different in another climate. Ragweed is the worst offender of late summer/early autumn in the eastern, southern, and midwestern US. Ragweed plants begin producing pollen as they mature in August.

Affirmation of allergic rhinitis depends largely upon an accurate patient history coincident with the pollination pattern of the offending plant. Molds, which are widespread in nature because they occur in soil or decaying organic matter, may propagate spores in a pattern dependent upon climatic conditions.

Examples of Agents Known to Cause Allergic Rhinitis

- Animal hair and tissue
- House dust
- Enzymes in laundry products
- Industrial organic chemicals
- Insect bites/contact with body parts
- Mites
- Mold spores
- Plant pollen

Table One

Classification of Chronic Rhinitis

| | |
|--|--|
| Atopic rhinitis <ul style="list-style-type: none">Seasonal allergic rhinitisPerennial rhinitis (allergic and non allergic) | Rhinitis from obstruction <ul style="list-style-type: none">Nasal septal deviationNeoplasmsForeign bodiesEnlarged adenoids |
| Infection rhinitis <ul style="list-style-type: none">Viral respiratory infectionsChronic purulent rhinosinusitis | Rhinitis of unknown origin <ul style="list-style-type: none">Idiopathic non-allergic rhinitis (vasomotor rhinitis)Wegener's granulomatosisAtrophic rhinitis |
| Rhinitis medicamentosa <ul style="list-style-type: none">Induced by topical agents | |
| Hormonal rhinitis <ul style="list-style-type: none">HypothyroidismPregnancy | |

Table Two

Signs and Symptoms

Intensity of symptoms of allergic rhinitis are proportional to the severity of sensitization. With mild susceptibility, victims may complain of nasal and/or ocular itching. Children may respond to allergy-induced nasal itching with a frequent upward rubbing motion of the tip of their nose, termed *allergic salute*. While extremely rare, if the child is permitted to do this continually, the action can lead to the development of a permanent transverse crease across the side of the nose. The repeated rubbing can also stretch tissues upward to cause the *Gothic arch*. In this condition, the upper lip and teeth push outward and upward and may result in an overbite. Or, sufferers may rub their eyes ceaselessly, leading to a bluish discoloration of the skin beneath the lower eyelids caused by venous congestion and edema around the eyes, called *allergic shiners*.

With more intensive sensitization, the symptom complex consists of sneezing (up to 10 or 20 repeated sneezes in rapid succession); itching of the nose, eyes, and throat with congestion; watery eyes; and clear discharge from the nose. When pollen counts are highest, the contiguous mucous membranes of the eyes, middle ear, and paranasal sinuses may also be involved. This can lead to conjunctival redness with unrelenting itching and pressure in the ears, checks, and forehead. Feelings of weakness, fatigue, malaise, irritability, inability to concentrate, loss of smell and taste, anorexia, "popping" or "clicking" of the ears, and chronic cough and clearing of the throat may also be experienced during severe exacerbations of the disease. Complications include sinusitis, otitis media, nasal polyps, enlarged tonsils and adenoids, and insomnia.

A Comparison of Symptoms of Upper Respiratory Tract Disorders

| Symptoms | Common Cold | Allergic Rhinitis | Sinusitis | Influenza | Streptococcal Pharyngitis |
|-------------|---|--|---------------------------------|-----------------------------------|--|
| Duration | 5-7 days self-limiting | weeks or months | days; months if untreated | 10 days | symptoms clear after 3 days |
| Cough | dry, hacking clear mucus | none, unless due to postnasal drip | none | severe | treat for 10 days |
| Fever | low grade (if any) | none | over 100°F variable | 100-104°F | over 100°F, spiking variable usually in children |
| Discharge | clear, copious rhinorrhea | clear rhinorrhea | purulent, thick yellow-green | purulent nasal; perhaps sputum | none |
| Pain | none, except a few aches prior to onset | none | pain over involved sinuses | generalized aches | in throat |
| Sore Throat | usually gone in 3 days | none | none | yes | red, inflamed |

Table Three

The complex of psychosocial effects suffered by the patient with allergic rhinitis has been called the allergic irritability syndrome. The syndrome includes mood swings, irritability, disruptive behavior, a short attention span, and poor school performance.

Symptoms of allergic rhinitis are similar to those of other upper respiratory tract disease including the common cold (Table Three). Although some of the symptoms of the other conditions may be self-treated with similar medications, others are not. Some conditions may require professional treatment, and each condition has its own means of prevention and control. Thus, it is important to eliminate it preferentially, as a primary means to control the symptoms.

Signs of allergic rhinitis are classic. The nasal mucosa appears pale and congested, but the tissue that lines the opening of the nose is not reddened or dry. The conjunctiva may be congested and edematous; the throat usually appears normal but it may be swollen. Swelling of the turbinates and mucous membranes with obstruction of the sinuses and eustachian tubes precipitates secondary infections of the sinuses and middle ear, respectively. This occurs in perennial, but is rarely seen in seasonal, disease. Nasal polyps can arise concurrently with edema and/or infection with in the sinuses and increase obstructive symptoms.

Other conditions also produce confusingly similar symptoms to allergic rhinitis including deviated septum, nasal polyps, tumors, and hypothyroidism (see Table Three). Whenever there is any

reservation about the cause of the patient's symptoms, it is best to recommend that a physician be consulted.

Mechanism of the Allergic Response

Histamine is a biologic amine and major mediator that has an effect on the vasculature of the nasal mucosa. Histamine is synthesized by decarboxylation of the amino acid histidine and store in mast cells in the mucous membranes to greatest extent. It is store in basophils in blood and other cells in the gastric mucosa as well. Although they are distributed throughout the body, mast cells are concentrated largely in the nose (200-400/mm³ tissue) and conjunctiva (500/mm³ tissue). This specificity to these tissues explains why the nose and eyes are particularly susceptible to allergic reactions.

When pollen contacts the moist mucosal surface, it becomes trapped there. Its outer coat is digested by enzymes such as lysozymes. This releases protein allergens which, presumably in nature, ease access of the pollen particles to the female pistils during the process of cross-fertilization. In humans, however, these proteins are antigenic and simulate the formation of specific immunoglobulin E (IgE) antibodies. IgE antibodies mediate the pathogenesis of allergic rhinitis. It is reported that each mast cell and basophil can concentrate 500,000 or more IgE molecules.

On re-exposure to antigen, the mast cells of patients with allergic rhinitis degranulate, releasing histamine and the number of other mediators of inflammation. These mediators stimulate the nasal end-organs to produce itching, sneezing, rhinorrhea, and

congestion. The immediate response to antigen occurs in over 90 percent of patients with a history of allergic rhinitis and positive skin tests.

Histamine contributes to rhinorrhea by inducing plasma leakage from blood vessels into the nose. It has been shown, however, that histamine does not cause plasma leakage by vasodilation or by an increase in vascular permeability after histamine challenge has been verified by identifying subsequent increases in albumin and nonsecretory IgA concentration. Histamine may stimulate rhinorrhea by a direct action to increase extravasation of plasma proteins, and indirectly by stimulating glandular secretion.

Additional potent inflammatory mediators involved in the allergic response are also released from mast cells and basophils. These include serotonin, heparin, eosinophil, and neutrophil chemotactic factors, prostaglandin D_2 , slow-reacting substance of anaphylaxis (SRS-A), platelet activating factor, leukotrienes and various proteolytic enzymes. Antihistamines antagonize histamine specifically, not the other mediators. Thus, this may help explain the incomplete relief of symptoms some patients gain from these drugs.

The autonomic nervous system plays a major role in producing symptoms associated with rhinitis. In fact, neural influences on the production of rhinitis have been implicated in allergic rhinitis, skier's nose (i.e., cold-induced rhinorrhea), gustatory (relating to the sense of taste) rhinitis, and non allergic rhinitis.

The body's vasculature is controlled by the sympathetic nervous system causing vasoconstriction. The parasympathetic nervous system causes vasodilation. The major neurotransmitter causing sympathetically-induced vasoconstriction is norepinephrine. Vasoactive intestinal polypeptide and acetylcholine are the parasympathetic neurotransmitters mediating vasodilation. The parasympathetic nervous system also controls nasal secretions from mucosal glands.

In practical terms, the sensory nerves incite a neural reflex which encourages nasal secretions. For example, intranasal instillation of capsaicin will decrease rhinitis by reducing the presence of the sensory neurotransmitter substance P. Gustatory rhinitis can be inhibited by ipratropium bromide, an anticholinergic drug

Continuing Education

Goals

The goals of this lesson are to discuss the etiologic factors associated with allergic rhinitis, and describe how the condition can best be prevented.

Objectives

At the conclusion of this lesson, successful participants should be able to:

1. differentiate the terms seasonal and perennial rhinitis;
2. select from a list, the etiologic and/or pathophysiologic factors associated with allergic rhinitis;
3. point out the common symptoms of allergic rhinitis;
4. identify the role of histamine in the allergic process; and,
5. demonstrate the ability to counsel patients on the causes and prevention of allergic rhinitis.



This program has been approved for one credit hour (0.1 CEUs) of ACPE approved continuing education. The Maryland Continuing Education Coordinating Council is an approved provider for continuing education programs for pharmacists by the American Council on Pharmaceutical Education. ACPE # 144-999-95-049-H04.

which is an antagonist to acetylcholine. Studies of ipratropium and atropine have been performed in non-allergic rhinitis and allergic rhinitis. In these conditions, the parasympathetic antagonist inhibits rhinorrhea, but not nasal congestion or sneezing. Neural control of the mucosal vasculature is unaffected by ipratropium. Challenge with methacholine, a parasympathetic agonist, has been noted to increase secretion, while pretreatment with atropine inhibits this response. In addition, methacholine does not affect nasal bloodflow, while sympathomimetic decongestant oxymetazoline (e.g., Afrin) decreases blood flow. So it appears that glandular secretion is under cholinergic control while the vasculature is controlled primarily by the sympathetic system.

Counseling Patients on Allergic Rhinitis

Pharmacists may be an allergic person's first contact with the healthcare system in diagnosing and treating the disease. It is important to recognize which symptoms are involved. Table Three may be a helpful review.

Avoidance of exposure to the offending allergen is the cornerstone of management and control of allergic diseases (Table Four). This is more feasible for antigens within the home than for airborne pollens. Seasonal sufferers have an advantage over perennial sufferers since they have some idea of what bothers them, what they can do to minimize symptoms, and when the symptoms will abate.

Controlling Exposure to Environmental Allergens

Bedroom

- close windows at night
- close forced-air heating vents or install filters over vents
- keep pets out
- encase mattress, pillows, & boxsprings in plastic coverings
- wash bedding in very hot water
- avoid feather or down pillows

Bathroom

- repair water leaks to reduce mold
- remove mildew and mold
- avoid use of aerosols

Living Room

- avoid sitting near fan, air-conditioner, or open window
- avoid sitting directly in front of fireplace or near heating vents
- avoid use of kerosene heaters, wood-burning stoves or fireplaces

General

- avoid use of strong-smelling cleansers
- avoid walking in woods and open fields
- do not bring ragweed-related plants (dahlias, chrysanthemums, and daisies) into home
- dust with damp or oiled cloth and vacuum twice weekly
- wash pets frequently and brush outdoors
- do not allow smoking in the home
- minimize number of items that collect dust
- choose furniture with a minimum of upholstery
- maintain room temperature before 70°F and relative humidity below 40% in warm weather
- use lightweight, washable curtains instead of heavy drapes

Table Four

Affected persons can be counseled to remove pets (cats are particularly troublesome) from the home, to avoid animal dangers, and to use air filtration devices to minimize the concentrations of airborne pollens. Travelling during times of low pollination, and arranging daily work by minimizing the time spent outdoors during the flowering house of individual plants will help avoid contact with airborne allergens.

Moving to another house or geographic area to eliminate a mold spore problem may be necessary. Few people are willing, however, to undertake a drastic change when substantial relief of symptoms is possible with pharmacologic intervention.

MP

Interactions

An Autumn Sampler

David A. Knapp, Ph.D., Dean, UMAB School of Pharmacy

A sampler of things going on in the School of Pharmacy this fall:

- Students are reporting back on their summer activities. Scott Goldfarb spend the summer as an APhA/ASP intern at Hoechst Marion Roussel.
- Michael Morton, Jareratt Silprasert, Juwon Lee, Stanley Shepperson, and Yoon Choe accompanied faculty members Ralph Blomster and Marvin Oed to Thailand for a study tour of hospital pharmacy and ethnobotany.
- Ruth Foster, Anne Graffunder, Chris Kahley, Suzanne Morsberger, Jin Choi and Sandra Werking attended the Utah School on Alcoholism and Other Drug Dependencies.
- Prashant Chikhale, James Polli, and Ashwiel Undie each received a prestigious new investigator program award from the American Association of Colleges of Pharmacy. Our faculty received three of only 18 awarded nationally.
- Delegate Nancy Kopp of the House Appropriations Committee visited the Maryland Poison Center in preparation for meetings underway now to find permanent funding solutions for the poison center's financial woes.
- The fall student Honors Convocation recognized 28 students for outstanding academic performance, including 4.0 grade points by William Knebel, Jeff Ensor, Laura Von Hagel, Michael Layton, and Aliza Fouzi. Professor George Dukes, president-elect of the American College of Clinical Pharmacy, addressed the awardees.
- Dr. Larry Augsburg, principal investigator of the School's multi-million dollar cooperative agreement with the Food and Drug Administration, traveled to Great Britain in October to present some of the results of his research.

- Pharmacy School Board of Advisor member Donald Kirson hosted the President's Roundtable at the Centre Club for UMAB president David Ramsay last month. He chaired a panel presentation on geriatric education issues that included a talk by Dr. Madeline Feinberg, director of the School's Edler Health program. Some 30 Baltimore business leaders attended the breakfast.
- Third-year Pharm.D. students got their teeth into the first phases of Integrated Science and Therapeutics, a new 16-credit, multiple-course offering designed to do just that. Students will systematically move through disease categories and study the best therapeutic approaches for each. Almost half of our faculty are involved in teaching this unique series.
- Governor Glendening and Mayor Schmoke were among the dignitaries at the ribbon-cutting for the \$54 million Health Science Facility now open on the UMAB campus directly across the street from Pharmacy Hall. The Governor reiterated that education and economic development were at the heart of his administration's agenda and that our campus was central to both. Dr. Ronald Guiles of our faculty is co-director of the NMR research facility in the new building.
- Speaking of economic development, growth in the School of Pharmacy's educational research and service programs over the last five years has created almost 200 new jobs for Maryland's economy. Thus, the School not only creates *future* economic value through education, it creates *current* economic value through today's programs and activities.



MP

Continuing Education Quiz

November 1995 -- Allergic Rhinitis Part I

This month's questions are taken from the article on allergic rhinitis that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. There is **no charge** for this quiz for MPhA members (non-members \$5.00). The completed quiz for this issue must be received by November 30, 1996. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE 144-999-95-049-1104.

Name _____

Address _____

City/State/ZIP Code _____

1. The time of year that is *least* likely to be an allergy season is:
 - a. summer
 - b. autumn
 - c. spring
 - d. winter
2. Which of the following statements is **true**?
 - a. Men suffer from perennial allergic rhinitis more often than women.
 - b. the incidence of seasonal allergic rhinitis is more prevalent than perennial allergic rhinitis.
 - c. Outbreaks of seasonal allergic rhinitis are unpredictable.
 - d. Allergies that cause rhinitis usually involve the lungs.
3. Which of the following is *least* likely to be a complication of allergic rhinitis?
 - a. nasal polyps
 - b. otitis media
 - c. pneumonia
 - d. sinusitis
4. The component of the body that digests the outer-coat of pollen to release the antigenic proteins is:
 - a. lysozymes
 - b. macrophages
 - c. granulocytes
 - d. basophils
5. The mediators of inflammation released during re-exposure to antigens are *least* to produce.
 - a. itching
 - b. rhinorrhea
 - c. sneezing
 - d. vasoconstriction
6. Histamine is stored to the greatest extent in which of the following types of cells?
 - a. melanocytes
 - b. erythrocytes
 - c. mast cells
 - d. T-helper cells
7. SRS-A is a(n):
 - a. investigational mast cell stabilizer.
 - b. synonym for basophils.
 - c. mediator of inflammation.
 - d. alternate name for ragweed pollen.
8. A patient who asks about the meaning of the term *perennial* should be told that this type of allergic rhinitis:
 - a. appears at any time of the year.
 - b. is not caused by an allergic reaction
 - c. does not affect the nasal mucosa.
 - d. is caused by perennial particles.
9. Which of the following immunoglobulins is most responsible for causing the symptoms of allergic rhinitis?
 - a. IgA
 - b. IgC
 - c. IgE
 - d. IgG
10. Histamine most likely contributes to the runny nose of allergic rhinitis by:
 - a. increasing nasal blood flow.
 - b. inducing plasma leakage from nasal blood vessels.
 - c. causing vasodilation of nasal blood vessels.
 - d. increasing vascular permeability.

CLASSIFIED ADS

Positions

Services

20% DISCOUNT on awards, plaques, trophies, and engraving to MPhA members. Call Rudy Winternitz, P.D. at Washington Trophy Center, (202) 966-1255.

PHARMACISTS: prn PLACEMENT AGENCY for temporary and permanent placement. Find out why more and more pharmacies are turning to PHARMACISTS: prn to fill all of their pharmacy staffing needs. Only 10% permanent placement fee, with 60 day guarantee. Temporary staffing services also available. Competitive prices. Rates for temps include all payroll taxes, FICA, workers' comp, liability insurance, etc. Almost a decade in providing pharmacy personnel services in every practice setting. Call PHARMACISTS: prn at (800) 832-5560.

WHAT DO STEAMED CRABS, the Orioles and *PharmaSTAT* have in common? They're all superior local products that cannot be duplicated outside of Maryland. *PharmaSTAT* is a Maryland company that has been providing quality pharmacists to Maryland pharmacies for 9 years. e have the largest active pool of pharmacist in the state, and have a proven track record. FT & PT pharmacists are available. Guaranteed lowest rates in the state! Need a pharmacist? Call *PharmaSTAT* at (410) 659-STAT.

PHARMACISTS REHABILITATION COMMITTEE For private, confidential referrals call (410) 727-0746 or (410) 706-7513.

Rx LICENSE TAGS are still available! A special benefit "for members only" that costs only a nominal fee. If interested, call Mary Ann at the MPhA offices toll-free, (800) 833-7587.

KIRBY LESTER KL8 FOR SALE tablet counter. Just reconditioned by manufacturer. Perfect operating condition. Will ship! \$450. Call (800) 231-1190.

Rentals

OCEANFRONT OC CONDO Fully furnished, 2 BR, 2 BA, cable TV, VCR, W/D, indoor pool, lighted tennis courts, sauna, gameroom. Convenient location, Seawatch at 115th Street. Great off season rates, call now for more information, (410) 647-6924.

Miscellaneous

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Placing an Ad

Have something to sell, rent, or trade? Need a pharmacist? Looking for a new position? MPhA members can place a classified ad in *The Maryland Pharmacist* for free. MPhA will remove member ads after six months unless otherwise notified by the member. Non-members may also place a classified ad. The ad placement charge is \$10 for a maximum of 50 words plus 50 cents per word greater than 50. To place an ad, call MPhA at (800) 833-7587.

Important Numbers

MPhA Offices
(410) 727-0746
(800) 833-7587 toll-free in Maryland
(410) 727-2253 FAX

MSHP Offices
720 Light Street
Baltimore, Maryland 21202
(410) 752-3318
(410) 752-8295 FAX

Maryland State Board of Pharmacy
4201 Patterson Avenue
Baltimore, Maryland 21215
(410) 764-4755
(800) 735-2258

Maryland Division of Drug Control
4201 Patterson Avenue
Baltimore, Maryland 21215
(410) 764-2890

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PHARMACIST AVAILABLE Bethesda pharmacist available for occasional relief. Weekends or evenings after six. Strong counseling skills. Prefer independent. Willing to travel on weekends. Call (301) 215-6775.

LICENSED PHARMACISTS Full- and part-time positions available in various Baltimore locations. Management background a plus. Positions may lead to various management career paths. Benefits include: medical package, flexible spending accounts for non-covered health and dependent care expenses, term life, and accidental death and dismemberment coverage, 401(K) plan, CE programs. Send resume to: Giant Discount Drug, Dept 541, PO Box 1804, Washington DC 20013 or call (301) 341-8700, ext. 1428. EOE.

LICENSED PHARMACISTS Opportunities, both full and part time, are available in selected store locations in Maryland, including two new locations in Baltimore. Positions offer the following benefits: excellent starting salary, comprehensive medical package, company paid retirement, 401(k) program and stock purchase. Mail resumes to: Jacqueline Rickers, Safeway Central Employment Office, 4501-E Forbes Blvd, Lanham MD 20706.

PHARMACY JOB OPPORTUNITIES Full and part-time, permanent and temporary, competitive pay and excellent benefits (accrued vacation pay, direct deposit, bonus plans, liability insurance, temporary health package, 401(k) plan, etc.) Positions in all practice settings. For more information, call PHARMACISTS:prn at (800) 832-5560.

PHARMACISTS WANTED by Pharmacy Corporation of America, a JCAHO accredited home infusion therapy and long term-care pharmacy, has an opportunity for a full time, clinically oriented pharmacist. Maryland licensure required. Newly licensed pharmacists welcome. Home care and QA experience a plus. Some on-call responsibilities. Excellent benefit package including health, life, vacation, 401(k) and stock options. Send resume and salary to: Pharmacy Corporation of America, 11240 Kiln Court, Beltsville, MD 20705, FAX (301) 210-3690. EOE/MF

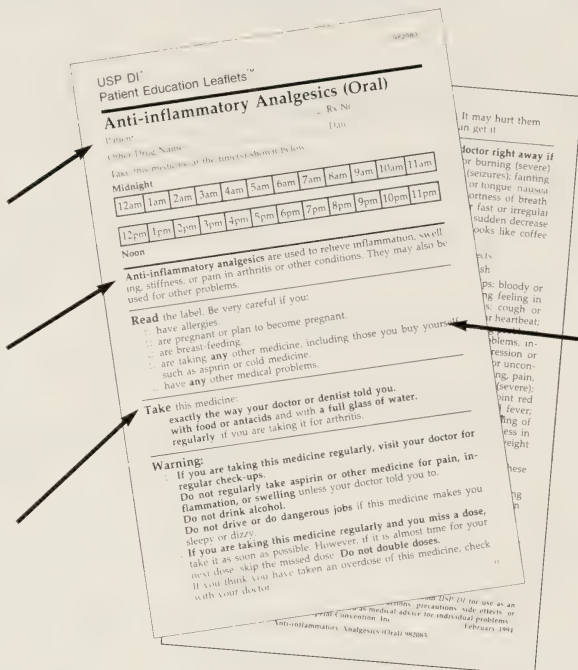
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NEWSLETTER

The Maryland Pharmacists Association

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Baltimore, Maryland 21201

(410) 727-0746

Welcome New Members

A special "hello" to 12 new MPhA members:

| | |
|----------------|------------------|
| Fred Barnstein | David Lewinter |
| Fred Batie | Joseph Parker |
| Kathy Bendebba | Ashok Ramkissoon |
| Marilyn Cox | William Ruth |
| Jason Kirby | Gerald Schonfeld |
| Howard Sherman | Paul Webster |

Call the Board

Last month's newsletter contained a list of several hundred pharmacists who, according to the Board of Pharmacy, have not renewed their Maryland licenses. The (800) number given for the Board of Pharmacy was incorrect. The correct number is (800) 542-4964. The local number is (410) 764-4755.

If you saw the name of a pharmacist on this list who is currently practicing, please have them call the Board immediately to avoid severe disciplinary actions.

Rite Aid Buys Revco

In a deal announced November 30, Rite Aid and Revco have entered into a definitive merger agreement to create the nation's largest drugstore chain with expected annualized revenues of over \$11 billion and more than 4,500 stores in 22 states. "The merger will increase Rite Aid's competitive advantage in our prescription benefits management subsidiary, Eagle Managed Care," said Martin Grass, board chairman and CEO of Rite Aid. In Maryland, Rite Aid has almost 200 locations; Revco has just under 50.

December 1995

The MPhA Newsletter is published monthly except during the months of July and August when the issues are combined. For information about any article contained herein, contact MPhA at (410) 727-0746 or toll-free at (800) 833-7587. President: James Tristani, P.D.; Chairman, Board of Trustees: Arnold Davidov, P.D.; Production Manager: David Miller, P.D..

Federal Employees Face More Mail Order

Effective January 1, 1996, the new Blue Cross prescription drug plan for federal employees and retirees who select the Standard Option and are also covered under Medicare Part B will require a 20 percent copayment for prescriptions filled at a Blue Cross/PCS preferred neighborhood pharmacy. Prescriptions mailed to National Rx Services, the mail-order company contracting with Blue Cross, will be dispensed without *any* copayment from the patient. The result? Approximately \$450 of out-of-pocket expenses to the average Medicare federal retiree who wants to continue to patronize their local pharmacist.

Organized pharmacy has been vocal in their opposition to this blatant attempt to disrupt the pharmacist/patient relationship. MPhA, NARD, NACDS, EPIC Pharmacy Network, and the Care Drug Centers have all been lobbying Congressional representatives to seek redress. In addition, NARD has researched and distributed a list of alternative plans available to federal employees and retirees other than the Blue Cross/Blue Shield Standard Option Plan.

What can pharmacists do? First, talk with your federal employees and retirees to let them know that Blue Cross is forcing them to use a drug delivery system that is not regulated by the Maryland State Board of Pharmacy; in other words, they don't have the security afforded by the extensive regulations and laws adopted by the Board to protect consumers. Second, ask them to write or call their Congressional representatives and express their displeasure at an insurance company that makes decisions affecting their choice of pharmacists without either their input or the input pharmacists. Third, share the information provided by NARD to help federal employees and retirees understand all their options and how the available choices affect their costs and access to prescription drugs and pharmaceutical care services.

AARP Mail-Order Goes Local

In an interesting twist, Retired Persons Services (RPS) and PCS are developing and testing an innovative and enhanced prescription drug program for members of the American Association of Retired Persons (AARP). The program will be called "Member Choice" and will, for the first time, provide AARP members with the opportunity to purchase prescription drugs from neighborhood pharmacies instead of using only the RPS mail order program.



Pay Attention!

Recently, the MPhA offices have been bombarded with phone calls from pharmacists who report that third-party contractors are paying at rates substantially below purchase cost or contracted reimbursement levels.

For example, a glitch in Maryland Medicaid's computer system -- allegedly due to a mistake on the part of their First Data Bank pricing service -- resulted in many prescriptions being reimbursed with outdated drug cost prices during early December. Problems with adequate and accurate pricing has been reported with Blue Cross/Blue Shield of Maryland, Express Scripts, Chesapeake Health Plan, and others.

Pharmacists must be vigilant! Only you can see whether or not you are being reimbursed properly. Excessively low MAC prices, unobtainable "AWP's", pricing company "oops", and just plain wrong information all lead to preventable losses. MPhA will continue to investigate problems brought to its attention. In addition, we are contacting the National Wholesale Druggists Association to seek their support in assuring a nationwide conformity with the definition of AWP.



Kelly Building Days Numbered

After 44 years MPhA's headquarters, the Kelly Memorial Building in downtown Baltimore, is slated for demolition by the University of Maryland Medical Systems sometime in late 1996.

Constructed in 1952 with funds contributed by Maryland pharmacists, the Kelly Building and its property is owned by UMMS. A buy-out of MPhA's lease, which includes relocation provisions, is currently under negotiation.

"While it's a tragedy to lose such a unique and special building, we have a terrific opportunity to plan for a new location that better meets the needs of members and our organization," says MPhA Building and Property Committee Chairman Joe Marrocco.

"We're going to be faced with some tough decisions over the next few months... should we remain on campus? stay downtown or move to the suburbs?"

etc." Architects retained by UMMS have developed several alternatives for MPhA, all of which include space for our museum collection, historic library, staff offices, and meeting facilities. MPhA hopes that the final building will provide sufficient space to house all Maryland pharmacy organizations.

As plans are finalized, MPhA will be launching a major capital fund-raising program for its new facility. Details will follow in future issues of the *Newsletter*.



Last Minute Present?

Looking for just the right holiday gift for the pharmacist or pharmacy buff on your list? Then MPhA's got just the thing for you -- a set of four, limited edition pharmacy art prints!

These ink line drawings by noted local artist Marian Quinn feature the E.W. Sterling Pharmacy in Church Hill, Sadler's Pharmacy in Laurel, the Kelly Memorial Building in Baltimore, and the University of Maryland School of Pharmacy as it appeared in 1886. The prints are 8x10 and suitable for framing; each one is hand numbered and signed by the artist.

The set of four **Historical Art Prints** cost only \$25.00 for members (\$50.00 for non-members) which includes shipping. Maryland residents must add sales tax to their order. To order, please call MPhA at (410) 727-0746 or (800) 833-7587. We can FAX you an order form or take your MasterCard or VISA.

Mid-Year Meeting

The MPhA Mid-Year Meeting is the *must* attend gathering of Maryland pharmacists! It's an opportunity to learn from and network with other pharmacists in a relaxed and enjoyable environment. Scheduled for Sunday, February 25, 1996 at the Loews Annapolis Hotel, this year's featured speakers include: Carl Schramm, Past President, Health Insurance Association of America; Louis Sesti, R.Ph., Vice President, PCS Health Systems; and Drs. Robert Kerr and David Roffman of the University of Maryland School of Pharmacy. In addition to the continuing education programs, the Mid-Year will feature presentations by Board of Pharmacy nominees and an MPhA House of Delegates business session.

Advance registration for this six credit program is \$50 for MPhA members (\$60 for non-members). Registration brochures will be mailed to pharmacists in late December.

Input Needed

Pharmacists willing to commit some time to help shape the future of the profession are desperately needed.

The Board of Pharmacy has a Pharmacy Practice Act Revision Task Force. This Task Force is looking at every aspect of pharmacy -- technicians, mailorder, substitutions, employee issues, labeling, robotics, etc.. The goal of the Task Force is to completely rewrite our Practice Act. If you'd like to serve on one of the Task Force's four sub-committees, please call MPhA at (800) 833-7587.

Earlier this year, local health department nurses sought the right to dispense drugs and samples. MPhA fought that and proposed, instead, that health departments work with local pharmacists to provide drugs. We now need two or three pharmacists, preferably with some relationship with a local health department, to help us work with the nurses, the Board of Nursing, and the Board of Pharmacy. Please call MPhA if interested.

Experiential Learning at the School of Pharmacy

Would you like students to benefit from your experiences as a pharmacist? Would you like to offer your pharmacy as a model for students to emulate?

WE'RE LOOKING FOR A FEW GOOD MEN AND WOMEN

Due to increased number of rotations, opportunities exist for new preceptors in:

- * Drug distribution and dispensing
- * Practice and business management
- * Ambulatory clinics
- * Patient (pharmaceutical) care
- * Specialty or non-traditional practice

For further information contact:

Marvin L. Oed, B.S.P.
Coordinator, Experiential Learning
UMAB School of Pharmacy
Century Building Room 313
506 West Fayette Street
Baltimore, MD 21201
Telephone: (410) 706-4192
Fax: (410) 706-0897

Always Double Check

Look-alike and sound-alike drug names can be misread or misinterpreted by a nurse reading doctors' orders or by a pharmacist dispensing physicians' prescriptions. Such misunderstandings can result in the administration of a drug not intended by the prescriber. Awareness of such look-alike and sound-alike drug names can reduce potential errors.

| | | |
|---------------|---------------|--------------------|
| Category: | <u>Mandol</u> | <u>Medrol</u> |
| Manufacturer: | Cephalosporin | Glucocorticoid |
| Generic Name: | Lilly | Upjohn |
| Dosage Form: | cefamandole | methylprednisolone |
| | Powder for | Tablets |
| | Injection | |

| | | |
|---------------|-------------------|-------------------|
| Category: | <u>Metaxalone</u> | <u>Metolazone</u> |
| Manufacturer: | Muscle relaxant | Diuretic |
| Brand Name: | Carnrick | Fisons |
| Dosage Forms: | Skelaxin | Zaroxolyn |
| | Tablets | Tablets |

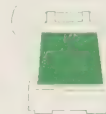
Contributed by Benjamin Teplitsky, R.Ph.

Phone Benefit

To better meet the needs of MPhA members who are part of AT&T's Profit by Association program, the company has announced that it is increasing the discounts on two popular telecommunications products.

Discounts on the AT&T Partner Plus and Partner II Communication systems are increasing from 5% to 10% off list price. In addition to the 10% discount, AT&T also offers:

- 5% off the list price for AT&T Partner Communication Systems
- 5% off the list price for AT&T Partner Communication Systems Voice Mail products, which are available with Partner Plus and Partner II systems. The discounts applies whether the voice mail products are purchased at the same time as the system or as add-ons.
- 10% off the list price for AT&T Merlin Plus Communications systems, and
- 15% off the list price for AT&T Merlin Legend Communications systems.



The AT&T Profit by Association program also offers special members-only discounts on a wide variety of business long-distance services, including domestic and international calling, 800 service local toll calls and fax services, to name just a few.

To find out more about how your business can take advantage of these discounts, as well as AT&T's quality and reliability, call your local AT&T account representative at (800) 722-7756, ext. 642Q.

Post Scripts

- R Bayer has introduced a new oral therapy for the treatment of non-insulin dependent diabetes mellitus (NIDDM). Precose™ (acarbose) is indicated as an adjunct to diet to lower blood glucose in patients whose hyperglycemia cannot be managed on diet alone. Precose is available in 50mg and 100mg tablets in bottles of 100.
- R Zestril has been cleared by the FDA for the treatment of acute heart attack patients. Administration of lisinopril within 24 hours of a myocardial infarction can significantly reduce the mortality of heart attack victims.

Upcoming Health Events

Telephone numbers are provided for additional information and promotional materials.

January

Glaucoma Awareness Week (708) 843-2020

February

American Heart Month (214) 373-6300

Children's Dental Health Month (312) 440-2500



Maryland Pharmacy Event Calendar

Dec 13-17 ACA Specialty Training Program in Respiratory Diseases. Call (703) 684-8603.

Dec 14 MPhA Board of Trustees Meeting, MPhA Headquarters, 7:00 pm.

1996

Jan 9 Poison Center Workshop, 10:00 am to 12:00 noon. Call (410) 706-7604 for information.

Jan 14 AZO Monthly Meeting, Holiday Inn Pikesville.

Jan 15-20 NARD Health Support and Appliance School and Exam, Orlando, FL. Call (800) 544-7447.

Feb 11 AZO Monthly Meeting, Holiday Inn Pikesville.

Feb 25 MPhA Mid-Year Meeting, Loews Annapolis Hotel, Annapolis, Maryland. Call (800) 833-7587.

March 10 AZO Fritz Berman Memorial Seminar, "Diseases of the Eye." Details to follow.

April 14 AZO Monthly Meeting, Holiday Inn Pikesville.

May 19 AZO Monthly Meeting, Holiday Inn Pikesville.

June 9 AZO Installation Banquet.

June 16-19 114th Annual MPhA Convention, *Charting a New Course*, Sheraton Ocean City Resort.

Happy Holidays!

The officers, trustees and staff of the Maryland Pharmacists Association wish you and yours the happiest of holidays and extend our hope that you have a healthy and prosperous 1996!

NEWSLETTER

The Maryland Pharmacists Association

650 Lombard Street

Baltimore, Maryland 21201



MARYLAND PHARMACIST

December, 1995

Vol. 71, No. 12



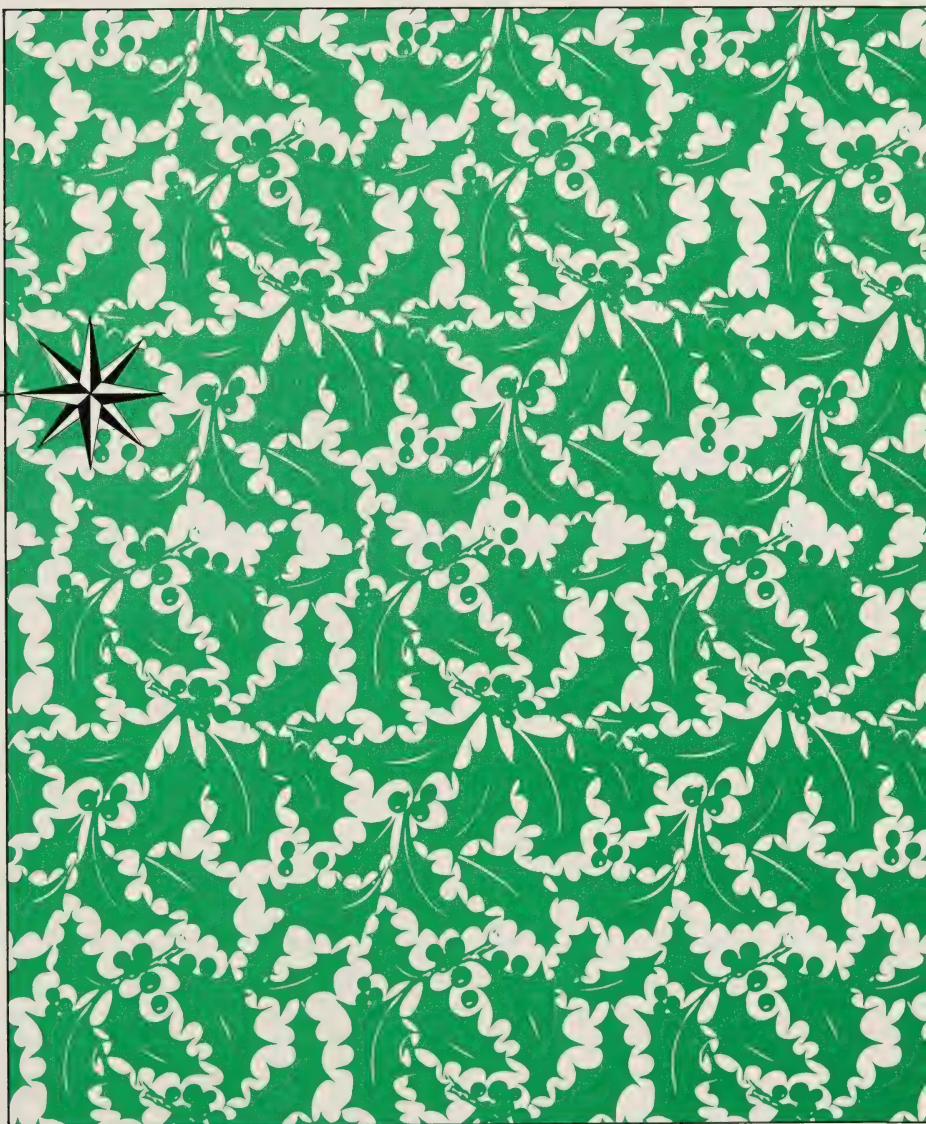
Rx Christmas
Carol

Medicine Chest
at Sea

Checking the List

Interactions

CE: Allergic
Rhinitis II



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MARYLAND PHARMACIST

The Official Publication of The Maryland Pharmacists Association

December 1995

4 President's Commentary

MPhA President Jim Tristani looks at all the things that MPhA does that many members don't even know about -- but that's just because we're doing our job.

5 A Pharmacy Christmas Carol

Forget Charles Dickens.... forget Tiny Tim.... This is *the* Christmas classic that every Maryland pharmacist needs to read.

11 Litigation Update

When is it a mistake and when is it negligence? Perspective, answers regular columnist and attorney David Brushwood, in this review of a recent legal decision.

12 Continuing Education

This month, we feature Part II of a multi-part examination of allergic rhinitis. Don't forget the CE quiz on page 30! It's *free* for all MPhA members and credits are ACPE approved.

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If Santa comes to Board of Pharmacy Secretary Mel Rubin's house this year, he'll need to bring a tractor trailer. You'll understand when you see his "wish list" for 1995.

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President's Commentary

Just Doing Our Job

We are all aware that the rapidly changing business environment has necessitated drastic adjustments by community pharmacists. However, many pharmacists still remain complacent about their future and their need to be involved in planning that future. The sad thing is, the "Oh, somebody'll take care of it" and "It's not my job" attitudes held by many pharmacists are outlooks that need and must be changed.

Let me shake you up a bit. How much has the business environment changed? In the past three years alone, Maryland lost 54 independent and 23 chain pharmacies. That's a loss of just under ten percent of our total pharmacy population. More are expected to close in the next several months. And with pharmacies go pharmacist jobs.

Still not alarmed? How about these little gems. In a recent economic impact survey of independent pharmacists done by MPhA in November, 87% of responding pharmacy owners and managers reported that they considered their pharmacy "at risk" if access to pharmacy networks continues to tighten and reimbursement continues to decline. Asked how they would cope with an integration of Maryland Medicaid recipients into managed care, 34% stated they would close the pharmacy or prescription department, 56% would reduce or lay off their pharmacists, and 65% would reduce or lay off technicians.

Not convinced yet? Ninety-three percent of those same survey respondents have been refused or had difficulty gaining access to pharmacy benefit networks. Seventy-one percent expect to be refused or eliminated from networks in the future.

Community practice owners and managers are and need to re-evaluate how and with whom they do business in today's competitive market.

A number of owners and managers have felt that cooperative organizations such as the very successful Care Drug Centers and EPIC Pharmacy Network can best meet their needs. These decisions may have validity if a strict "dollar and cents" yardstick is applied. Tossed aside is membership in MPhA.

I understand that mindset as a pharmacy owner myself. Anything to cut costs. After all, what does MPhA do anyhow?



James Tristani, P.D.
1995-96 MPhA President

Many pharmacists, including pharmacy owners and managers, have overlooked the real value of the Maryland Pharmacists Association. In their desire to have "economic" issues resolved, they've forgotten the true impact of the so-called "professional" issues MPhA deals with on a daily basis. This organization has traditionally been the most vigilant watchdog to prevent the profession's assault by various agencies, regulatory boards, and outside parties. As I reported last month, several groups of nurses are seeking dispensing privileges. That kind of "professional" issue might have an intangible economic impact today but, if neglected by

organized pharmacy, could lead to further eroding of the role of pharmacists and the need for pharmacies.

All pharmacists, and especially pharmacy owners and managers, should carefully reflect when our dues requests come across their desks. Membership in MPhA may not offset dollar-for-dollar your dues investment next year. But your continuing ability to even be in business is the direct result of that investment and MPhA's actions.

After all, that's our job.

MP

A Pharmacy Christmas Carol

Mary Chaffee, R.Ph.
Springs Drug Store, Burton, Michigan



nce upon a time, on the eve of Pharmacy Week, Old Ed Scrooge sat busily in his office while counting the daily receipts of Scrooge Pharmacy and keeping an eye on his intern, Rob Cratchit. Although the fall's chill was coming in, Ed still hadn't turned on the furnace.

"Happy Pharmacy Week, Uncle," cried a cheery voice. It was the voice of Scrooge's nephew, who entered so quickly that this was the first indication of his approach.

"Bah," said Scrooge. "Humbug."

"Surely you don't mean that!" said the nephew. "What is Pharmacy Week?" asked Scrooge. "A time to pay your MPhA dues; a time for watching your gross margin fall while seeing another ridiculous insurance contract come in the mail?"

"Come to the BMPA dinner dance tomorrow night." pleaded the nephew. "Perhaps your old friends can cheer you up."

"Bah, humbug! Be gone with you !" bellowed Scrooge in return.

Well after nine o'clock, when the customers had long since departed, Rob Cratchit was putting on his coat to leave. "You'll want tomorrow night off for that banquet, I suppose?" asked Scrooge. "If it's convenient, sir."

"It's not convenient," replied Scrooge. "But I suppose I have no choice. Be here all the earlier tomorrow morning."

The overworked intern promised he would, and Scrooge walked out with a growl. He shuffled home as the fog and darkness thickened around him and the cold became intense. Scrooge ate his Budget Gourmet dinner at home in solitude while looking over his ledgers, then retired to his gloomy bedroom. Having heard strange noises below, Scrooge closed his door and locked himself securely in the house. Being satisfied with that, he put on his PJ's and went to bed.

Suddenly, a clanking noise rang deep down below, as if some person were dragging a heavy chain up the basement stairs. The basement door flew open with a bang, and Scrooge heard the noise much more loudly, coming up the next set of stairs towards his door. Through his bedroom door came the apparition, and Scrooge could see that it was the ghost of his business partner, Bob Marley. Marley's body was transparent and had a long chain wrapped around his waist.

"Why do you walk the earth and come to trouble me?" Scrooge implored.

"How is it that I appear before you in a shape that you may see, I may not tell, however, I come to warn you. You will be haunted by three spirits. Expect the first one when the bell tolls one." With that, the apparition drifted backwards and faded away.

Old Ed Scrooge went down to examine the locked door, only to find it undisturbed. "Humbug," he said and went back to bed to fall instantly asleep.

As foretold by Bob Marley's ghost, when the clock struck one, a strange figure appeared at the foot of Scrooge's bed. "Who and what are you?" Scrooge demanded.

"I am the Ghost of Pharmacy Past."

"Long past?"



"No, your past." The apparition put out its strong hand as it spoke and clasped him gently by the arm. "Rise and walk with me."

With that, the ghost and Scrooge passed through the bedroom wall and stood in an old pharmacy, complete with a soda fountain.

"Good heavens !" said Scrooge, clasping his hands together as he looked about him. "This is where I started out in the profession !"

Across the store was the young intern Scrooge in a starched white jacket, engaged in conversation with an elderly woman. Young Scrooge was explaining how her new heart medication made her heart beat stronger. She thanked him profusely, patted his hand and made her way out into the crisp fall afternoon. A young woman entered with her crying infant and Scrooge poured her a potion to relieve its colic.

Why did he rejoice to see these sights? Why was ol' Scrooge's heart warming to see these of things that had been?

In bounded two of his classmates engaged in a cheerful banter. Old Scrooge turned to the Ghost and said excitedly, "There's Dewayne Robinson and Al Kent, to be sure !" "Yo ho, there Eddie !" Al said to young Scrooge. We've come to give you a ride to the MPhA CE meeting."

"Ready whenever you are, Big Al!" young Scrooge replied. "I hear there's a great speaker tonight." With that, off they strode, looking like The Three Musketeers.

"I have seen your nobler aspirations fall off one by one, until the master passion, Gain, engrosses you, have I not?" inquired the Ghost. Scrooge retorted angrily, "What then? Even if I have grown so much wiser, what then? Take me back. Haunt me no longer!"

Scrooge then became conscious of being exhausted and overcome by irresistible drowsiness, then of being alone in his bedroom. He sank into a heavy sleep.

Awakening mid-snore, Scrooge heard the bell toll two and woke as the second messenger arrived, sent to him at Bob Marley's intervention. He pulled back the blankets to find that his bedchamber had under-gone a surprising transformation. In place of wall and ceiling hung so much greenery and apple trees that it looked like an orchard. Brightly hued fall leaves were scattered amongst the trees and heaped upon the floor were bushels of apples and neat rows of pumpkins.

"Come in!" commanded the ghost. "I am the Ghost of Pharmacy Present. Look upon me."

Scrooge reverently did so. The ghost was clothed in a flowing burnt-orange robe bordered with rabbit fur. Its dark brown curls were long and free, and its sparking eyes and cheery voice gave it a joyful air.

"Touch my robe."

Scrooge did as he was told and held the robe fast.



Both he and the ghost were instantly transported to a bustling Rite Aid pharmacy. Several pharmacists were busy at computer screens, transcribing prescriptions which were appearing on the screens.

"Where are those prescriptions coming from?" demanded Scrooge.

"Twelve hundred doctors' offices are computer linked to Rite Aid Pharmacies," the Ghost answered.

"Surely this is in the future, not the present, Spirit."

"Oh, but you are wrong, my good man. It is astounding where modern technology has taken us in a short time. I could show you much more of this, but our time is running short. Now let me show you where you are today, Mr. Scrooge."

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With that, Scrooge and the Ghost of Pharmacy Present were whisked back to familiar Scrooge Pharmacy. Ed Scrooge was there at his computer grumbling over his rebillings, too busy to properly counsel his patients.

"I give them the information sheet that the computer generates now," Scrooge offered as an explanation.

"Do you think little Jason Flanders knows how to properly use his inhaler. And did you know that Gladys O'Malley can't read? How is she going to know that she shouldn't take her Maalox with the Cipro prescription you just dispensed for her?"

Scrooge's head hung down in shame at his comment.

From the folds of its robe, the ghost brought forth a small boy. Wretched, frightful and miserable, the boy knelt down at the ghost's feet and clung to the outside of the garment.

Scrooge started back, appalled. "Spirit, is he yours?"

"He is all pharmacists," said the spirit, looking down upon him. "This boy is Ignorance. Beware of him and all his kind. On his brow I see written Doom, unless the writing is erased."

Scrooge then looked about him for the ghost and saw it not. He was again quite alone in his gloomy bedchamber. A throbbing headache came upon him, so he took some Tylenol PM and laid back down.

When the bell tolled three, another phantom gravely, silently approached Scrooge. Shrouded in a deep black garment, is was completely concealed in the cloth, except for one outstretched hand.

"Are you the Ghost of Pharmacy yet to come?" inquired a groggy Scrooge. The spirit did not answer, but pointed onward with its outstretched hand.

"Ghost of the Future," he exclaimed. "I know your purpose is to do me good, and I hope to be a different man from what I was. Will you not at least speak to me?" The ghost gave no reply. The hand pointed straight before them. "Lead on," said Scrooge. "Lead on."

Suddenly, Scrooge and the Ghost of Pharmacy Future were in the center of a small town. Groups of people were scattered along the sidewalk, engaged in conversation.

The spirit stopped beside a pair of elderly women standing in front of a gigantic vending machine. Observing that the hand was pointed to them, Scrooge advanced to listen to them talk.

"This is so convenient," said a portly woman in a pink dress as she stuffed a plastic card into the gleaming machine. She punched in a number as she continued, "I can come at any time of the day or night and get my prescription filled. Besides, the pharmacist never really talked to me about my prescriptions anyway. I wonder whatever happened to him?"

As she spoke, a bag containing her prescription popped out into the plastic bin at the bottom. On in was attached an information sheet and her receipt.

"I'm not sure," replied the other woman. "I think Ed is working for Medco, the company that services the APM machines."



"Spirit !" Scrooge said. "This is a horrible scene. This lesson is not lost on me. Please take me back!"

The phantom spread its dark robe like a wing, withdrew it, and revealed a brightly lit conference room in a large hospital.

"I'm afraid the news is bad," the director began nervously. "The administration has forced us to lay off many of our pharmacists. Since Medco is supplying the pre-mixed IV bags and most of you refused to go on clinical rotation, we need only a few pharmacists to check carts and do STAT orders. I tried to go to bat for you, but since most of your work could be done by technicians, the administration didn't feel it could justify the cost of your positions."

There amongst the group was a middle-aged Rob Cratchit, with his jaw slack and color draining from his face.

"Spirit, are these shadows of things that will be, or are they shadows of things that may be only?" The ghost was immovable as ever. "Spirit!" he cried, clutching tight at its robe, "Hear me! I am not the man I was. Assure me that I may change. Let me prove that these shadows you have shown me can be altered!"

"I will honor pharmacy in my heart and keep it all the year. I will remember that it is a noble profession, not just a job. I will do things differently -- intervening and problem solving in a more caring way. I will provide pharmaceutical care and document it, starting now! I won't wait for reimbursement, I will make the commitment now. Please tell me that it's not too late!"

Holding his hands in a last prayer to have his fate revised, he saw an alteration in the phantom's robe, which shrunk, collapsed and dwindled down to a bedpost.

Yes! The bedpost was his own. The bed and room were his own, too. Best of all, the time was his own to make amends in!

Scrooge bounded down the stairs, busily clothing himself, giddy as a schoolboy. He went dancing down the street to his pharmacy and regarded everyone with a delighted smile.

Rob Cratchit, Scrooge's intern, was waiting by the back of the store. "Mr. Scrooge?"

"Good day, my dear intern, and happy Pharmacy Week to you!" Scrooge replied. "I think we should start this day with a raise in salary, don't you think?" Rob Cratchit stuttered in shock, "I-I..."

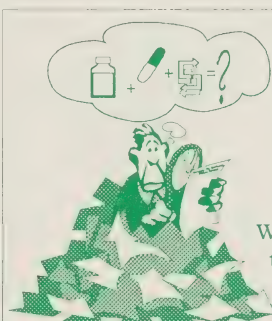
"Well, of course. You worked so hard this summer for me. And how about that consultation room you've been trying to create? It's about time for that, too. I think I'll call the MPhA and see if it's not too late to sign up for the next CE program. We need to get caught up to the 1990's. Say, were there any tickets left for the dinner dance?"

Cratchit was dumbfounded.

Ed Scrooge was better than his word. He made the changes and even more. He served his profession well with thorough patient consultations and participated in MPhA committees when asked. Some people laughed to see the changes in him, but he heeded them little because he knew that nothing ever happened for good as which some people did not have their fill of laughter. In truth, his own heart laughed, too, and that was good enough for him.

He had no further visitations from the spirits but never forgot his lessons from them. From that day on, it was always said of him that he knew how to keep pharmacy well, if any man possessed the knowledge. Whether we be from hospital, retail, employee or manager, may the same be truly said of us all. **MP**

"A Pharmacy Carol" was revised and reprinted with permission from the Michigan Pharmacists Association. Mary Chaffee, a pharmacist at Springs Drug Store in Burton, Michigan, serves as a member of the Board of Trustees of the Michigan Society of Community Pharmacists.



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Litigation Update

Wanton Negligence or a Simple Mistake

Nobody likes to dispense an incorrectly filled prescription.

However, it can and does happen. But at what point does a misfill move from an unfortunate mistake to become an act of negligence?

The Supreme Court of Alabama recently affirmed a judgement in the amount of \$255,000 against a pharmacy company. The company was sued by a woman who alleged that one of the pharmacy's pharmacists had negligently and wantonly misfilled her prescription. The basis of the complaint was that the pharmacy had failed to initiate sufficient institutional controls over the manner in which prescriptions were filled and that, as a result, the patient's prescription for a breast cancer medication had been incorrectly filled.

The company admitted negligence in misfilling the prescription, however the company disputed the "wantonness" on the part of the pharmacist. In Alabama (and most other jurisdictions), "wantonness" means "reckless or conscious disregard of the rights or safety of others."

According to the facts as set out by the court, the pharmacist entered information from a prescription for Tamoxifen into her computer incorrectly and as a result she dispensed Tambacor by mistake on three occasions.

The pharmacist knew that the prescriber was an oncologist, and, although she recognized the obvious potential problem, she did not call the prescriber to confirm the prescription.

The company management had evidence of numerous incidents of incorrectly filled prescriptions; however, it failed to share this information with the stores in the chain. Instead of providing the information to its stores, a company representative merely encouraged the pharmacists once a year to "be careful." Was this wantonness? Yes, said the jury. And the court affirmed the verdict.



David B. Brushwood, R.Ph., J.D.

The result of this case demonstrates how important it is to have meaningful quality assurance mechanisms in place in every pharmacy. Incident reports should be generated each time a mistake is identified; pharmacists should be evaluated on a regular basis; and strategies should be identified to reduce or eliminate sources of error. Simply telling people to "be careful" is not good enough. Institutional controls must exist to detect and rectify problems in pharmacy services. Failure to implement such controls increases exposure to liability. **MP**

Based on: *Harco Drugs, Inc. v. Holloway*, 1995 Ala. Lexis 343 (August 11, 1995). Copyright 1995, David B. Brushwood. All Rights Reserved. Reprinted from *Dickinson's Pharmacy*, September, 1995.

Allergic rhinitis (hay fever) is the sixth most prevalent chronic condition in the U.S. With more than 50 million sufferers, allergic rhinitis outranks heart disease in incidence. It is classified as seasonal (acute) or perennial (chronic).

Classical manifestations of nasal and ocular congestion and itching, sneezing, and other symptoms are caused largely by histamine released from its physiological storage sites. Drug therapy is directed toward lessening or blocking the body's response to this.

Since a cure is not available at this time, the current goal of therapy in treating allergic rhinitis is to control symptoms. Pharmacologic intervention may be necessary when symptoms interfere with normal daily activities. Most sufferers respond to an antihistamine alone, or combined with a decongestant when the antihistamine fails to provide sufficient relief. Other drugs used to control symptoms include intranasal corticosteroids and mast cell stabilizers.

Antihistamines

As the benchmark of therapy for allergic rhinitis, antihistamines are the most commonly used drugs (Table 1) to control symptoms. The mechanism of action of antihistamines is blockade of histamine competitively at its H-1 type of receptor. Therapy is maximized when the drugs are started early and are taken without interruption throughout the pollen season. If the antihistamine is present in

sufficient concentration when the stimulus for histamine release is generated, symptoms of allergy should be lessened. Antihistamines exert no significant effect on other mediators of inflammation.

Antihistamines vary in potency, pharmacokinetic parameters, sedation and anticholinergic effects. Individuals may respond to greater extent and experience fewer adverse effects to a drug of one particular chemical group than another (see Table 1).

Sedation and anticholinergic effects differ greatly when comparing the originally available antihistamines, such as diphenhydramine, with the more recently marketed drugs such as astemizole, loratadine and terfenadine. In this lesson, the original antihistamines will be referred to as first-generation and the more recent drugs as second-generation.

Allergic Rhinitis Part II -- Treatment

*Thomas A. Gossel, R.Ph., Ph.D., Dean
Ohio Northern University*

*J. Richard Wuest, R.Ph., Pharm.D.
Professor of Pharmacy Practice, University of Cincinnati*

A professional development program made possible by
an educational grant from **SEARLE**.

Antihistamine activity is achieved within 30 minutes of oral administration. Action peaks in 1 to 2 hours and persists for 3 to 6 hours. The piperazine derivatives and astemizole, loratadine, and terfenadine may provide relief of symptoms for 12 to 24 hours. Some of the first-generation drugs stimulate their own metabolism, so tolerance can develop with continuous administration.

The first-generation antihistamines are highly lipophilic (lipid soluble), and therefore, cross the blood-brain barrier readily. Drowsiness is the most common adverse effect (especially the ethanolamine derivatives), followed by anticholinergic symptoms (e.g., dry mouth, blurred vision, urinary retention, constipation). These are reported to be the most troublesome and the primary reason for noncompliance with dosage instructions. All first

generation antihistamines require a warning statement on their label about the potential for impairment of mental ability and physical performance.

The second-generation antihistamines differ significantly from the older drugs in that they are significantly lipophobic (less lipid soluble). They do not cross the blood-brain barrier readily and, therefore, produce less sedation and anticholinergic effects. The reason for the difference between the two generations is based on their lipid solubility and ability to enter CNS blood flow.

Histamine is a neurotransmitter in the CNS that is at least partially responsible for maintaining wakefulness and arousal. Drugs that block central histamine receptors decrease alertness. Some antihistamines block cholinergic and alpha-adrenergic receptors as well. Both actions can contribute to drowsiness.

First-generation antihistamines are sometimes used for their adverse effects. For example, drowsiness can help those with mild insomnia fall asleep. Therefore, diphenhydramine is used in OTC sleep aids. Anticholinergic action dries excessive nasal secretions which has been the basis for their use in treating cold symptoms. Applied topically, antihistamines have a local anesthetic effect and alleviate itching.

Persons with acute narrow-angle glaucoma, enlarged prostate gland, and chronic obstructive pulmonary disease such as chronic bronchitis and emphysema risk worsening their disease by using drugs that have anticholinergic activity. Cholinergic blockade inhibits

Antihistamine Classification

| Chemical Class/ Generic name | Representative Trade names | Sedative Effect | Anticholinergic Effect |
|---------------------------------|----------------------------|-----------------|------------------------|
| First Generation | | | |
| <i>Alkylamines</i> | | | |
| Acrivastine | in Semprex-D | low | moderate |
| Brompheniramine | Dimetane | low | moderate |
| Chlorpheniramine | Chlor-Trimeton | low | moderate |
| Dexchlorpheniramine | | low | moderate |
| Triprolidine | in Actifed | low | moderate |
| <i>Ethanolamines</i> | | | |
| Clemastine | Tavist | moderate | high |
| Diphenhydramine | Benadryl | high | high |
| <i>Ethylenediamine</i> | | | |
| Tripeleminamine | Pyrabenzamine | moderate | low to none |
| <i>Phenothiazines</i> | | | |
| Methdilazine | Tacaryl | low | high |
| Promethazine | Phenergan | high | high |
| Trimoprazine | Temaril | moderate | high |
| <i>Piperazines</i> | | | |
| Hydroxyzine | Atarax | moderate | low |
| <i>Piperidines</i> | | | |
| Azatidine | Optimine | moderate | moderate |
| Cyproheptadine | Periactin | low | moderate |
| Second Generation | | | |
| Astemizole | Hismanal | low | low |
| Loratadine | Claritin | low | low |
| Terfenadine | Seldane | low | low |

Table One

aqueous humor outflow which elevates intraocular pressure and aggravates narrow-angle glaucoma. It increases urinary retention which further complicates the problem of increased prostate gland size, making micturition even more difficult. By reducing respiratory secretions, they become more viscous and difficult to expectorate. At one time, asthma was included in this warning. However, allergists petitioned FDA to remove the warning since it was confusing to some asthmatics who receive antihistamines for treatment of their condition.

Because of additive effects, first-generation antihistamines should be used with caution when other CNS sedatives, including alcohol, are being taken. This group of antihistamines can potentiate anticholinergic drugs. Monoamine oxidase inhibitors prolong and intensify both the CNS depressant and anticholinergic effects of first-generation antihistamines.

Children may experience excitation rather than sedation with antihistamines because their central inhibitory neurons may not be developed fully. The result can be that excitatory

Patient Counseling for Antihistamines

- * Antihistamines are used to relieve the runny nose, watery eyes and sneezing of hay fever.
- * Most antihistamines can be taken without regard to meals. If this medication causes stomach upset, it can be taken with food. For CLARITIN and HISMANAL: the manufacturers of these products state that they should be taken on an empty stomach (with a glass of water) at least 1 hour before or 2 hours after a meal.
- * Some people may experience dizziness, blurred vision or drowsiness from antihistamines. If they do, they should be careful driving or performing hazardous tasks. Alcoholic beverages can increase the drowsiness effect.
- * Some people may experience dry mouth from taking antihistamines. If they do, sucking on hard candy, chewing gum or using saliva substitute can alleviate the problem.
- * Antihistamines can make skin more sensitive to sunlight or sunlamps. It is best to use a suitable sunblock product (of at least SPF 15) if the person is going to be exposed to sunlight for a prolonged period of time. They should not use a tanning booth.
- * OTC cough/cold, hay fever, allergy, sleep aid, or motion sickness medications contain antihistamines and should not be used in with other antihistamines.
- * There are few side effects reported with antihistamines. However patients should tell their doctor if they experience blurred vision, loss of appetite, persistent headache, difficulty in urinating, mental confusion, if any other bothersome or unusual effect.

Table Two

neurons predominate, resulting in ataxia, hallucinations and seizures. Patient counseling information is listed in Table Two.

Decongestants

Sympathomimetic amine decongestants alleviate nasal and ocular congestion. Decongestants also counterbalance drowsiness associated with antihistamines.

Sympathomimetic amines stimulate alpha-adrenergic receptors on subepithelial precapillary sphincters, arterioles and venous sinuses of vascular smooth muscle. This constricts dilated vessels, the exudate is reabsorbed, and tissue hyperemia decreases. In the nose, airways are enlarged and breathing is easier. Systemic decongestants are indirectly-acting sympathomimetics which release endogenous vasoconstrictors.

Decongestants are indicated for temporary relief of nasal congestion associated with allergic rhinitis. They can be applied topically or administered systemically. Decongestant action following systemic administration is slower in onset, but longer lasting. Some topical decongestants (oxymetazoline and xylometazoline) also possess extended length of activity. Oral decongestants are preferred when therapy is required for longer than three days because they do not cause rebound congestion (rhinitis medicamentosa) that occurs from overuse of locally applied drugs. Topical decongestants should be reserved, ideally, for persons with severe congestion (complete obstruction) when relief is crucial, such as bedtime when congestion interferes with sleep.

Healthy individuals may use systemic decongestants without problems. They must be used only with caution in persons with diabetes, heart disease, hypertension, and enlarged prostate. Since they are

sympathomimetic amines, decongestants can increase conversion of glycogen into glucose which can worsen hyperglycemia in patients with diabetes. They can aggravate cardiac arrhythmias and angina. Because they are vasoconstrictors, decongestants can interfere with control of patients with high blood pressure.

Sympathomimetic amines can have an additive effect on the heart and blood pressure to that caused by elevated serum thyroid levels. As with antihistamines, decongestants can make micturition more difficult in males with enlarged prostate.

To place all this in proper perspective, none of these potential adverse effects contraindicate concurrent use. However, FDA believes the public should be advised of the possibility and requires a warning to this effect on the labeling of OTC decongestants. Patients with these diseases should include their physician in the decision on whether or not to use them. If the physician decides the benefits of the decongestant outweigh the risks, the intent of the warning has been met and the decongestant can be used. Alternatively, a topical decongestant could be recommended since it is less likely to cause systemic effects and aggravate these diseases as the systemic agents would.

Decongestants can cause irritability and insomnia as principal side effects. Concurrent administration of a monoamine oxidase inhibitor can potentiate their cardiovascular action leading to hypertensive crisis, intracranial hemorrhage, even death. Concurrent use of a decongestant with a monoamine oxidase

inhibitor is contraindicated. A drug interaction precaution must appear on the labeling of OTC decongestants stating this. Patient counseling information is listed in Table Three.

Patient Counseling for Decongestants

- * Decongestants are used to relieve the nasal stuffiness of hay fever.
- * Most decongestants can be taken without regard to meals. If this medication causes stomach upset, it can be taken with food.
- * The controlled release dosage forms should be swallowed whole, not crushed or chewed.
- * There are few side effects reported with decongestants. However, patients should tell their doctor if they experience persistent headache, restlessness, prolonged nausea, difficulty in sleeping or urination, or any bothersome or unusual side effects.

Table Three

Mast Cell Stabilizers

Cromolyn (e.g., Nasalcrom) stabilizes mast cells to prevent to release of histamine and other mediators of inflammation to protect against the allergic response. This effect may result from cromolyn blocking the transport of calcium across cell membranes. Cromolyn is devoid of sedation and other adverse effects associated with antihistamines and decongestants.

Used prophylactically during the pollen season, cromolyn nasal spray confers a significant reduction in nasal sensitivity and symptoms including obstruction, rhinorrhea, sneezing, and itching. Activity is limited, however, and

severe symptoms may not be alleviated completely. Treatment with cromolyn should begin 2 to 4 weeks before exposure to allergens and continue throughout the allergy season for optimal response.

Necrodromil is also a mast cell stabilizer. While indicated for the treatment of asthma, it is reported to be effective in prophylaxis and long-term therapy of allergic rhinitis. In addition to mast cell stabilization, necrodromil also causes activation of different inflammatory cells such as eosinophils, macrophages, and platelets. At the time of preparation of this lesson, necrodromil nasal spray was in clinical trials but had not yet been approved for marketing.

Mast cell stabilizers are especially useful during long pollen seasons. They are safe, with only occasional nasal irritation and headache reported. Patient counseling information is listed in Table Four.

Corticosteroids

Topical intranasal corticosteroids (Table Five) are the most potent medications available for treatment of allergic rhinitis. Topical corticosteroids offer the advantage of delivering the drug to its site of action while minimizing hypothalamic-pituitary-adrenal (HPA) axis suppression and other adverse systemic effects. Outcomes with the various corticosteroid preparations are basically the same. Differences between products involve formulation, delivery systems, and duration of action.

Patient Counseling for Intranasal Cromolyn

- * Intranasal cromolyn is used to relieve or prevent the discomfort of allergic rhinitis.
- * This medication contains instructions on its proper administration. These instructions should be followed.
- * Important information on the use of the nasal spray includes:
 - removing the dust cap and safety slip from the bottle before using it.
 - gently blowing the nose to clear the nostrils just before using it.
 - carefully inserting the nasal applicator into the open nostril.
 - inhaling deeply through the nostril while activating the unit.
 - repeating the above in the other nostril.
 - replacing the dust cap and safety clip after use.
- * To help prevent contamination from nasal secretions, the applicator can be rinsed in warm water after each use.
- * It is important that the patient give the medication a chance to work. It may take several weeks before improvement is noticed.
- * For the first week, if they experience excessive nasal congestion, the patient can use a decongestant nasal spray just prior to this medication.
- * There are few side effects reported with intranasal cromolyn. However patients should tell their doctor if they experience continued nasal irritation; bloody discharge from the nose; burning or excessive sneezing; difficulty in breathing; headache; swelling of the face, hands or feet; skin rash; or any other bothersome or unusual effect.

Table Four

These drugs ameliorate nasal symptoms of allergic rhinitis. Clinical studies suggest that they inhibit the late-phase nasal reaction after exposure to allergens; reduce the number of mast cells, basophils and eosinophils in the nasal mucosa; inhibit leukocyte activation and

Patient Counseling for Intranasal Corticosteroids

- * Intranasal corticosteroids are used to relieve or prevent the discomfort of allergic rhinitis.
- * Each aerosol and spray has its own set of instructions which should be followed when administering the medication.
- * Important information that is common to these products include:
 - removing the dust cap and shaking the container well before using it.
 - gently blowing the nose to clear the nostrils just before using it.
 - closing one nostril with a finger, and carefully inserting the applicator into the open nostril.
 - activating the unit
 - breathing gently inward through the nostril and out through the mouth.
 - repeating the above in the other nostril.
 - replacing the dust cap after use.
- * To help prevent contamination from nasal secretions, the applicator can be rinsed in warm water after each use.
- * It is important that the patient give the medication a chance to work. It may take several days before improvement is noticed.
- * For the first 2-3 days, if they experience excessive nasal congestion, patients can use a decongestant nasal spray just prior to this medication.
- * There are few side effects reported with intranasal corticosteroids. However, patients should tell their doctor if they experience continued nasal irritation; bloody discharge from the nose; excessive sneezing; difficulty in breathing; persistent sore throat; swelling of the face, hands or feet; skin rash; muscle cramps or pain; or any other bothersome or unusual effect.

Table Five

leukotriene and prostaglandin production; and reduce the sensitivity of irritant receptors and secretory mechanisms to cholinergic stimulation.

Intranasal corticosteroids are more effective in preventing symptoms than in counteracting them.

Occasionally, local irritation, stinging, sneezing, drying, burning, and epistaxis (nasal bleeding) have been reported with the aerosol units. These effects may be minimized with a saline nasal spray between administration of the topical steroid, or switching to the nasal sprays which are aqueous solutions. There is no evidence to date of mucosal atrophy. Overgrowth of *Candida albicans* is reported rarely.

Relief of symptoms should be achieved within one to two weeks. Patients need to understand that immediate improvement in symptoms will not occur, and that absolute compliance with their physician's instructions is necessary. Other patient counseling information is listed in Table Five. Products are listed in Table Six.

Immunotherapy

Known also as hyposensitization, desensitization, or "allergy shots", immunotherapy involves giving repeated subcutaneous injections of gradually increasing concentrations of the offending allergens. Effectiveness is proportional to the size of the cumulative dose, and specific for the particular antigens employed.

Benefit is obtained from altering the immunologic reactivity of an allergic individual so that there will be less response to the naturally offending allergen. This occurs by stimulating an increase in concentration of IgG antibodies. Immunotherapy also reduces IgE levels at mast cells, reduces mast cell and basophil degranulation in response to allergen challenge, and stimulates T-lymphocyte suppression of IgE antibodies. Once protection has been achieved, patients receive maintenance injections at 4 to 6 week intervals to keep symptoms under control.

Patient Counseling

When counseling on OTC antihistamines, patients should be informed that they can modify histamine-induced symptoms. However, to be most effective, the agents should be started early in the hay fever season. Because people are different biologically, there is wide variation in response to different products.

Nasal Sprays & Aerosols Containing Corticosteroids for Allergic Rhinitis

| Trade Name | Active Ingredients(s) | Type of System | Strength |
|-------------|-----------------------|----------------|-------------|
| Beconase AQ | beclomethasone | pump | 42mcg/spray |
| Beconase | beclomethasone | aerosol | 42mcg/spray |
| Flonase | fluticasone | pump | 50mcg/spray |
| Nasalcort | triamcinolone | aerosol | 55mcg/spray |
| Nasalide | flunisolide | pump | 25mcg/spray |
| Rhinocort | budesonide | aerosol | 50mcg/spray |
| Vancenase A | beclomethasone | pump | 42mcg/spray |
| Vancenase | beclomethasone | aerosol | 42mcg/spray |

At the time of preparation of this lesson, Vancenase AQ Forte pump was in the "approvable stage", and not yet marketed.

Table Six

Antihistamine or decongestant products with a single ingredient, in a regular-release dosage form, should first be recommended. After the most effective active ingredients are identified, i.e., those with the best action and fewest adverse effects, sustained-release dosage forms and/or multiple ingredient products may then be chosen.

Immunotherapy, intranasal steroids and mast cell stabilizers should be restricted to individuals with more persistent and severe disease whose symptoms cannot be managed suitably with antihistamines or decongestants.

MP

Continuing Education

Pharmacists can earn one hour (0.1 CEU) of ACPE approved continuing education credit for this lesson by completing and returning the quiz on page 30 of this issue. There is no charge for this benefit to MPhA members (non-members: \$5.00 fee).

Goals

The goals of this lesson are to discuss the treatment of allergic rhinitis with pharmacologic agents. The basis for immunological therapy is also explained.

Objectives

At the conclusion of this lesson, successful participants should be able to:

1. identify drugs used to modify symptoms of allergic rhinitis;
2. select from a list, the pharmacologic and toxicologic mechanisms, and pharmacokinetic parameters, of the drugs discussed;
3. identify the therapeutic role of the drugs discussed and immunotherapy in treatment of allergic rhinitis; and,
4. choose from a list, important points to convey to patients about treatment of allergic rhinitis.



This program has been approved for one credit hour (0.1 CEUs) of ACPE approved continuing education. The Maryland Continuing Education Coordinating Council is an approved provider for continuing education programs for pharmacists by the American Council on Pharmaceutical Education.

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Interactions

Reaching Out to Pharmacy in Thailand

David A. Knapp, Ph.D., Dean, UMAP School of Pharmacy

The School of Pharmacy has reached out to pharmacy around the globe by joining nine other schools of pharmacy in the United States to further the development of pharmacy education in Thailand. The agreement, more formally known as the Thai/US Pharmacy Education Consortium, is supported by the Royal Thai Government to enhance basic research and clinical programs of the Thai faculty and students in pharmacy. The ultimate, long-term goals of the program are to increase the number of pharmaceutical scientists and practitioners in Thailand by strengthening its network of pharmaceutical education. The result will be to strengthen educational research and practice and, consequently, health care in Thailand. Over 125 Thai pharmacists will seek advanced degrees through the consortium over the next 12 years.

The Thai students who come to Maryland will be prepared for advanced education in graduate and Pharm.D. programs through their interactions with our faculty and students. Recently, we were very pleased to accept the first class of students and one visiting scientist who serve on the faculty at Chiang Mai University, Chulalongkorn University, Ubon Ratchathani University, and Khon Kaen University. Mr. Preecha Varjabhaya, the Minister Counselor of Education at the Thai Embassy, along with members of his staff, Ms. Achara Raftabhan and Ms. Kannikar Pawattananiti joined President Ramsay, Dean Knapp, and faculty to welcome the future leaders of Thai pharmacy.

Dr. J. Edward Moreton, Professor of Pharmaceutical Sciences and the School's Thai Program Coordinator, has worked from the Consortium's inception to ensure that Maryland learns about pharmacy in Thailand and to exchange ideas

among U.S. and Thai students and faculty to promote international collaboration. According to Dr. Moreton, the people of Thailand recognize the need to improve their health care system especially in rural provinces. The School is expecting six



Shown is the contingent of Thai visitors in the Leavitt Memorial Garden. Back row, left to right: Dean David Knapp, Dr. Edward Moreton, Mr. Marvin Oed, Dr. Ralph Blomster, Mr. Vithaya Kulsomboon. Front row, left to right: Ms. Laksana Charoenchai, Ms. Leena Lesslasvatanakij,

Ms. Supatra Porasuphatana, Ms. Maneerat Rattanamahattana, Mrs. Kanoom Niwatananun, Mr. Wirat Niatananun.

additional students from Mahidol University to arrive at UMAP in the spring for short-term study. It is planned that over the next ten years, the consortium will bring 90 to 150 pharmacy faculty from Thailand's ten public institutions to earn doctoral degrees and develop joint research programs at the consortium's ten U.S. universities.

Two School of Pharmacy faculty, Dr. Ralph Blomster and Mr. Marvin Oed, along with a group of UMAP pharmacy students, visited hospital pharmacies, botanical gardens, and remote jungle regions in Thailand during the summer in a student exchange program sponsored by the consortium. The Thai students who are currently at the School of Pharmacy are: Umaphorn Boonyasopum, Laksana Charoenchai, Vithaya Kulsomboon, Leena Leelasvatanakij, Kanokporn Niwatananun, Wirat Niwatananun, Suthiphong Pangkanon, Kampanart Panasedthaned, Supatra Porasuphatana (visiting scientist), Maneerat Rattanamahattana, Nattee Sirisuth, Wandee Suttarangsee.

MP

This article was written by Mary Franks, Assistant to the Dean, UMAP School of Pharmacy



Pharmacy At Sea

The Role of Maritime Pharmacists in the History of the Ship's Medicine Chest

George F. Archambault, Pharm.D., LL.D., Captain
US Public Health Services (Retired)

The roles of pharmacists, physicians, dentists, nurses and others in the development of the *Ship's Medicine Chest and Medical Aid at Sea* is of such importance to be worthy of recording. It presents an important insight into the unique role that pharmacists have played in providing pharmaceutical care throughout the history of the United States.

An Act of Congress approved July 20, 1790, provided that a medicine chest arranged by a reputable apothecary be placed on each American flag vessel of 150 tons and upward which was navigated by 10 or more persons. The legislation specified also that each chest have with it a set of directions for the administration of each item. The first edition of *The Ship's Medicine Chest and First Aid at Sea*, as we know it today, was prepared by the Marine Hospital Service in 1881 for use aboard ships that did not carry a physician. Since then, the handbook has been revised and rewritten several times, to bring it up to date in terms of improved care of the sick and advances in modern medical knowledge.

The handbook proved to be so useful that a second edition, revised and expanded, appeared in 1904. The work continued to be revised and new editions issued over the course of the twentieth century. In addition to the two editions previously noted, the National Library of Medicine holds editions published in 1929, 1947 (reprinted with additions and changes in 1955), 1978, and 1984.

The current edition of *The Ship's Medicine Chest and Medical Aid at Sea* describes in simple, non-technical terms the anatomy of the human body and the functions of the various organs. It furnishes guidance for the treatment and after-care of the diseases and emergencies most frequently met at sea. Considerable space is devoted to preventative medicine, personal hygiene, and sanitation afloat. Specific instructions for requesting medical advice by radio are also given in detail. The closing chapter concerns procedures surrounding to births and deaths at sea.

Proficiency in first aid has long been required as a qualification for masters, mates, and other licensed officers on American merchant vessels. Medical officers of the Public

Health Services customarily give applicants for license as officers of the American Merchant Marine the necessary instructions in first aid, examine them at the conclusion of the course, and certify to their training and proficiency in first aid.

Medical Advice by Radio

The plan for giving medical advice by radio to masters of vessels on the high seas was suggested in 1921 by Captain Robert Huntington, Principal of the Merchant Marine School of the Seamen's Church Institute in New York.

Seagoing vessels are required by law to be equipped with standard medicine chests. The standardization of medicine chests facilitates the giving of medical directions by radio to ships at sea.

Since 1925 the Public Health Service had furnished medical advice by radio to ships at sea. Any vessel not carrying a physician, that had sickness on board, could get in touch with designated Marine Hospitals of the Service by radio, describe the illness aboard, and receive medical advice as needed.

Within recent years medical advice by radio to ships at sea has become such a commonplace practice that it is now considered to be routine. When this plan was first inaugurated, many letters of appreciation were received by the Public Health Service from patients who had been treated in accordance with instructions by radio as well as from ships' officers upon whom fell the responsibility of supervising the care of sick persons on their vessels.

Revisions

The guide *The Ship's Medicine Chest and First Aid at Sea* was published in 1947 as a joint project of the United States Public Health Service and the War Shipping Administration. Assistant Surgeon General R.C. William's text, *The United States Public Health Service: 1798-1950*, published by the Commissioned Officers Association of the USPHS in 1951 chronicles the historical development of the guide through its creation in 1790 and its subsequent revisions.

Eight years after the 1947 joint cooperative publication, *The Ship's Medicine Chest and First Aid at Sea* was reprinted with a number of changes. Dr. Otis Anderson, Assistant Surgeon General, Chief, Hospital Division and Dr. Halsey Hunt, Captain, USPHS, Assistant Chief, Division of Hospitals were directly responsible for this revision. Their input and drive led to the addition of newer medications and first aid treatments of injuries that superseded the older outdated ones.

The 1955 edition retained the 1947 version intact and updated by actual content substitution as follows:

- A complete revision of the "Standard List of Drugs and Chemicals" for all types of vessels;
- Current regulations of the Public Health Service regarding medical care for its beneficiaries and foreign quarantine activities and the listing of hospitals and outpatient facilities of the USPHS;
- Updated material, printed on colored (green) paper,

The Ship's Medicine Chest

Drugs Added in the 1955 Revision

Aluminum Hydroxide Gel, Dried, USP - Tablet
 Ascorbic Acid Tablets, USP
 Benzalkonium Chloride, USP (Zephiran)
 Benzathine Penicillin G, N.N.R. (Bicillin or Permapen) - Tablets, Cartridge*
 Benzoic and Salicylic Acid Ointment, half strength
 Chloroquin Phosphate Tablet, USP (Aralen)
 Dimenhydrinate, NNR (Dramamine)
 Diphtheria Antitoxin, USP
 Mercuric Oxide, Yellow Ointment, USP - Ophthalmic
 Meth-Dia-Mer Sulfonamides, NNR - Tablets
 Neomycin Ophthalmic Ointment, NNR
 Oxytetracycline, NNR (Terramycin)
 Paraldehyde, USP
 Penicillin G, Benzathine, NNR (Bicillin) - Tablets, Cartridge*
 Penicillin with Aluminum Monostearate
 Poultice, Dental (Poloris)
 Procaine Hydrochloride Injection, USP
 Succinylsulfathiazole Tablets, USP (Sulfasuxidine)
 Triasyn B Tablets, USP
 Tripelennamine Hydrochloride, USP (Pyribenzamine)
 Zinc Oxide Paste, NF

*Appropriate special hypodermic syringe and needles for use with cartridges were also required to be available.

Table One

covering: Chapter III, Hygiene, Sanitation and Preventive Medicine; Chapter IV, The Sick Bay and Medicine Chest; Chapter VI, First Aid and Emergency Treatment of Injuries; Chapter VII, The Classification and Treatment of Diseases; and Chapter IX, Births and Deaths at Sea.

This 1955 update contained the following dedication:

DEDICATED TO: THE AMERICAN MERCHANT SEAMAN AT WHOSE BEHEST THE MARINE HOSPITALS WERE FIRST ESTABLISHED IN THE YEAR 1798 AND WHOSE HISTORY AS A PUBLIC HEALTH SERVICE IS A RECORD OF THE PROGRESS OF MEDICINE AND SANITATION IN THE UNITED STATES.

At the time, a later revision was planned. To that end, the 1955 edition "welcomed comment on any of the procedures and medicaments in this revised edition." As a commissioned officer of the USPHS at the time of the revision, I was responsible for overseeing the update of Chapter IV: The Sick Bay and Medicine Chest. Twenty-one medications were added to the chapter (see Table One)

Despite plans for a revision, the actual document was maintained until 1978 (23 years later), when the *Ship's Medicine Chest and Medical Aid at Sea* was completely updated and issued by the Department of Health Education and Welfare, Health Services Administration, Bureau of Medical Services (HEW Publication No. (HSA) 78-2024.

The Ship's Medicine Chest

Detailed Information Provided with 1955 Revision

ASCORBIC ACID TABLETS, USP

Unit: Tablet 50 mg

Usual Package: 500 tablets in a suitable container

Amount on hand at beginning of voyage: 1000 tablets

Use: For use in the emergency treatment of scurvy. It is unlikely that this disease will be encountered to any great extent among members of the American Merchant Marine. Their diets are sufficiently well balanced to preclude the vitamin-deficiency diseases, unless an individual himself unbalances the diet as a result of abusive use of alcohol, or by habitually selecting parts of the diet (such as starches, sugars or other carbohydrates of which he may be particularly fond) to the exclusion of others (such as fruits and meats). Scurvy may be encountered in shipwreck survivors.

Dosage: One 50 mg. tablet daily is the usual protective dose; 2 to 3 tablets (100 to 150 mg.) daily is the recommended therapeutic dose.

BENZATHINE PENICILLIN G, NNR

Unit: Tablet 200,000 units

Usual package: Vial of 36

Amount on hand at beginning of voyage: 3 vials

Use: Give only on radio advice and in dosages recommended. Usual dose is one tablet every 8 hours.

CHLOROQUIN PHOSPHATE, USP

Unit: Tablet 0.25 gm

Usual package: Bottle of 1,000

Amount on hand at beginning of voyage: 2 bottles

Uses: See insert before Chapter VII on the treatment of malaria. Four tablets at once followed by two tablets in 6 hours in treating an acute attack; then two tablets daily for 3 days.

METH-DIA-MER SULFONAMIDES, NNR

Unit: Tablet 0.50 gm

Usual package: 500 tablets in a bottle

Amount on hand at beginning of voyage: 2 bottles

Uses and Dosage: To be substituted wherever sulfadiazine is recommended in the 1947 revision. See page 110 and Chapters VI and VII. Use this drug only when indicated on advice by radio. Advising physician will elect choice of therapy - an antibiotic (penicillin or oxytetracycline) or meth-dia-mer sulfonamides, NNR tablets. *Note:* The use of any sulfonamide as a dusting powder in open wounds is no longer an acceptable practice (make marginal note at page 187)

OXYTETRACYCLINE, NNR CAPSULES

Unit: Capsule 0.25 gm

Usual package: Bottle of 100

Amount on hand at beginning of voyage: 2 bottles

Use: Give only on radio advice and in dosage recommended. Usual dose is one capsule every 6 hours. *Note:* Insert marginal notation at page 126 with reference to benzathine penicillin G, penicillin with aluminum monostearate, and oxytetracycline; also see insert preceding Chapter VII for indications of use.

PARALDEHYDE, USP

Unit: Bottle

Usual package: Bottle, 1/4 lb

Amount on hand at beginning of voyage: 1 bottle

Uses: For marked restlessness and excitement. For dosage, see "Delirium Tremens," insert before Chapter VII.

SUCCINYL-SULFATHIAZOLE, USP

Unit: Tablet 0.50 gm

Usual package: Bottle of 500

Amount on hand at beginning of voyage: 2 bottles

Use and Dosage: Used in the treatment of food poisoning and bacillary dysentery. Give 8 tablets 2 to 4 times a day until bowel movements are normal.

TRIASYN B TABLETS, USP

Unit: Tablet with 2 mg thiamine HCl, 3 mg riboflavin, 20 mg nicotinamide.

Usual package: Bottle of 500 tablets

Amount on hand at beginning of voyage: 2 bottles

Use and Dosage: For use in the treatment of beriberi (thiamine hydrochloride) cheilosis (riboflavin) and pellagra (nicotinamide).

TRIPLENNAMINE HCL, USP

Unit: Tablet 50 mg

Usual package: Bottle of 100

Amount on hand at beginning of voyage: 2 bottles

Uses: Often useful in allergic conditions and in treating antibiotic reactions. See "Hay Fever" and "Hives" insert before Chapter VII. Obtain advice by radio before using.

BENZALKONIUM CHLORIDE, USP

Unit: Bottle of 12.8 % concentrate.

Usual package: 8-ounce bottles

Use: Replaces anti-infective solution described on page 113. Follow manufacturer's directions on bottle. To make 1 gallon of the commonly employed 1:1000 solution, place 1 ounce of benzalkonium chloride (12.8 percent concentrate) in a glass container, and add distilled water to make 1 gallon; mix well.

The Ship's Medicine Chest

Detailed Information Provided with 1955 Revision

BENZOIC AND SALICYLIC ACID OINTMENT, HALF STRENGTH

Unit: Pound

Usual package: Pound

Amount on hand at beginning of voyage: Pound

Use: In the treatment of ringworm (see page 388) and other parasitic skin diseases. A thin layer should be rubbed gently on the affected skin; apply several times daily. Caution: Avoid overuse of various kinds of ointments, lotions, or solutions - severe chemical and other types of dermatitis may result.

DIMENHYDRINATE, NNR

Unit: Table 50 mg

Usual package: Bottle of 100

Amount on hand at beginning of voyage: 2 bottles

Uses: For treatment and prevention of dizziness and seasickness. (See "Dizziness" insert preceding Chapter VII.)

MERCURIC OXIDE, YELLOW OINTMENT

Unit: 1 percent ointment

Usual package: 1/8-ounce tube

Amount on hand at beginning of voyage: 6 tubes

Uses: A local antiseptic used in the treatment of stys, inflammation of the edges of the eyelids and inflammation of the mucous membrane of the eyes.

NEOMYCIN OPHTHALMIC OINT., NNR

Unit: 1/8-ounce tube

Usual package: 1/8-ounce tube

Amount on hand at beginning of voyage: 6 tubes

Uses: To replace Eye Ointment, Anesthetic and Antiseptic, page 118. For pain, use anesthetic eye drops as indicated on page 117.

POULTICES, DENTAL

Unit: Package

Usual package: 12 in package

Amount on hand at beginning of voyage: 2 packages

Uses: For local application in place of aspirin as indicated on page 372 of text.

ZINC OXIDE PASTE, NF

Unit: Pound

Usual package: Pound

Amount on hand at beginning of voyage: Pound

Use: A nontoxic, protective, mildly astringent and antiseptic paste employed in a large variety of diseases and irritations of the skin.

BENZATHINE PENICILLIN G, NNR

Unit: Cartridge (600,000 units)

Usual package: Single cartridges

Amount on hand at beginning of voyage: 10 cartridges

Uses: Give on radio advice only. Usual dose is one cartridge injected intramuscularly. Sterile needle furnished with each dose. Appropriate special syringe and needles for use with cartridges must be available.

DIPHTHERIA ANTITOXIN, USP

Unit: Vial

Usual package: 20,000 units per vial

Amount on hand at beginning of voyage: 5 vials

Use: Treatment must be prompt and adequate. In general the average dose is 100 units of antitoxin per pound body weight in mild cases and up to 5 times this amount for severe forms. It should be administered in a single dose, intravenously, except in the very mild case where intramuscular injection is satisfactory. Caution: Under no condition should this antitoxin be used intravenously without radio advice.

PENICILLIN WITH ALUMINUM MONOSTEARATE (PAM) - INJECTABLE

(Combined crystalline and procaine penicillin in oil)

Unit: Procaine penicillin G, 300,000 units. Crystalline penicillin potassium 100,000 units in oil with aluminum monostearate.

Usual package: 1 cc. disposable syringes

Amount on hand at beginning of voyage: 12 syringes

Uses: This preparation combines crystalline penicillin for high initial blood levels and procaine penicillin for repository effect. Give on radio advice only.

PROCAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION, USP

Unit: 1 percent procaine hydrochloride with epinephrine 1:50,000

Usual package: 2 cc. ampule

Amount on hand at beginning of voyage: 24 ampules

Use: As a local anesthetic to be used only upon advice by radio.

The title was altered slightly during the 1978 update to emphasize the greater medical care needed aboard ships often goes beyond basic first aid.

James H. Erickson, M.D., M.P.H., Assistant Surgeon General, Director, Bureau of Medical Services at that time (1978) wrote the foreword of the revised test. His message is reproduced here.

"The Federal Government has furnished medical care to sick and disabled American merchant seamen since 1798. In 1790 eight years before the establishment of the U.S. Marine Hospital Service, legislation provided for the placement of a medicine chest on each American flag vessel over 150 tons navigated by 10 or more persons. It was not until 1881, however, that the first medical handbook was prepared for use aboard ships.

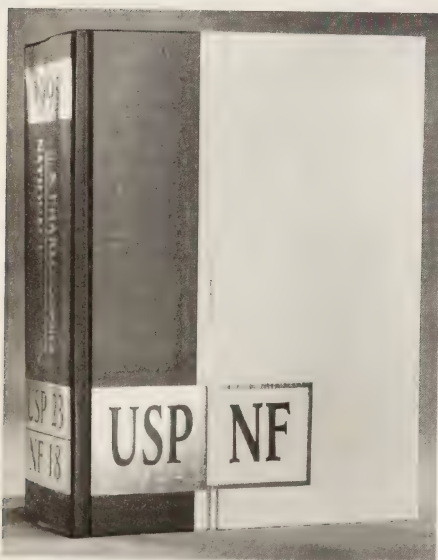
The initial edition of our present volume was published under the title, *Handbook for the Ship's Medicine Chest*. Revised editions have been produced from time to time that incorporated new medical procedures and therapies to meet the changing needs of seamen and the conditions under which they worked.

This edition represents a major effort by many professionals to bring together in one volume the very latest principles of medical diagnosis and treatment. It is intended primarily for the information and guidance of the Master and other licensed and certificated crew members who directly or indirectly may be responsible for medical care on merchant ships at sea.

I urge all who may act as medical attendants aboard merchant vessels to study this volume carefully, and to seek professional advice by radio as soon as possible, whenever it may be necessary. The successful accomplishment of a ship's mission is directly related to the health and welfare of its crew.

As always the U.S. Public Health Service stands ready to assist in every way possible."

Six USPHS officers provided the medical review and three special consultants assisted in the preparation and consultation of much of the material on the Technical-Editorial Advisory Committee. Included on the committee for this 1978 edition were pharmacists Richard Bertin, R.Ph., Ph.D., and Captain Arthur Dodds, Ph.G., Ph.C., who along with myself, still reside in Maryland.



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It is to be noted that over the years, pharmacists have played important roles in not only the history of the Ship's Medicine Chest and First Aid at Sea as depicted here, but also as well in other areas of the U.S. Public Health Service such as the Marine Hospitals, the Indian Health Service, International Health, Foreign Quarantine, and Radiopharmacy and Nuclear Medicine.

In September 1994, the *Commissioned Corps Bulletin* carried the following item of interest concerning the *Ship's Medicine Chest and Medical Aid at Sea*:

Editorial Board Appointed for "The Ship's Medicine Chest and First Aid at Sea"

The publication, 'The Ship's Medicine Chest and First Aid at Sea' has been edited and published by the Public Health Service (PHS) since 1881. The current edition is out of print and has not been revised since 1987. Although formerly used almost exclusively by the Merchant Marines, this text is now widely used by private and public sailing and cruising vessel personnel as their key to medical care while at sea or away from port. This is a very visible and important function for PHS.

This Editorial Board once again included pharmacists. Captain Steven R. Moore, OSG/OASH, co-author with Frederick Abramek of the article "The United States Public Health Service Commissioned Corps Pharmacists: The Evolution of Professional Practice" in the publication *Pharmacy in History*

(Volume 34, 1992, No.2), was selected along with Commander John T. Babb, BOP, and Captain Melvin Lessing, ODER/FDA.

The role of the pharmacist in the successful production and use of *The Ship's Medicine Chest* is a little known means by which pharmacists have assisted in providing patient care and saving lives for many years. We can be proud that Maryland pharmacists have had an active role in this part of history.

MP

About the Author

George F. Archambault, Pharm.D., J.D., has had a long and distinguished career as an international authority in pharmacy and law. He served as the editor and Washington correspondent for the journal *Hospital Formulary*, a position he held from 1967 and 1978. From 1979 to 1984, he was Washington correspondent for *Drug Intelligence and Clinical Pharmacy*. Archambault for seven years was pharmacy consultant to the Executive Medical Officer of the United Mine Workers of America Welfare and Retirement Fund. In this capacity he was responsible for developing and implementing a basic drug list (i.e., formulary) in cooperation with the US Pharmacopeial Convention. Serving over one-half million United Mine Workers' beneficiaries through some 1,768 hospital and clinic pharmacies in seven states, Archambault was responsible to the Executive Medical Director for overseeing a drug expenditure totaling more than \$10 million. Patient drug profiles and formulary drug prescribing became part of the pharmacy program under Archambault's leadership.

One of Archambault's many outstanding contributions to pharmacy was the development of pharmacy standards (*Conditions of Participation*) for Medicare, which he did while he served in the Bureau of State Services and as a Pharmacy Liaison Officer to the Office of the US Surgeon General.

Archambault studied pharmacy at the Massachusetts College of Pharmacy and law at Northeastern University. In addition to earning degrees in pharmacy and law, Archambault received honorary doctorate degrees in pharmacy from the Philadelphia College of Pharmacy and Sciences and from the Massachusetts College of Pharmacy. He also received an honorary doctorate of law degree from Temple University. Upon graduation from pharmacy school Archambault served on the faculty of the Massachusetts College of Pharmacy for 17 years.

As a practitioner of both pharmacy and law, Archambault maintained a private law practice for six years and he practiced hospital pharmacy for 15 years. He was a commissioned officer in the US Public Health Service (USPHS) and was Director of Pharmacy for three years at the USPHS Hospital in Boston. He served for many years as chief of the Pharmacy Branch, Division of Hospitals, Bureau of Medical Services, USPHS, Washington, DC.

The listing of offices held by Archambault in professional associations is extensive. Among them are the presidencies of both the American Pharmaceutical Association (APhA) and the American Society of Hospital Pharmacists (ASHP). He was a member of the US Pharmacopeial Convention for more than 3 decades and a trustee for 10 of those years.

Among Archambault's many honors, he received both the Remington Honor Medal and the H.A.K. Whitney Lecture Award, the highest honors by the APhA and the ASHP. He also had been awarded the highest honors by the USPHS, the Distinguished Service Medal, and by the Association of Military Surgeons, the Andrew Craigie Award. In 1972, the American Society of Consultant Pharmacists honored Archambault by establishing the recognition of outstanding and meritorious contributions to this specialty.

Now in his 85th year, he continues to serve pharmacy as a consultant and writer.



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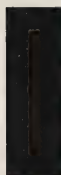


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Making a List And Checking it Twice

*Melvin Rubin, P.D., Secretary and Commissioner
Maryland State Board of Pharmacy*



It's that time of year when a certain all-seeing gentleman begins reviewing the behavior of pharmacists to

see whose been naughty and whose been nice. And I'm not talking about the Board inspectors, either. So, I thought it would be timely to go over a couple of folks' wish-lists for the holiday season.

A word of caution. A prerequisite for being allowed to read this article is a full acknowledgment that you understand that it is tongue-in-cheek, a spoof, not meant to be taken literally, does not exist, and should not in any way be taken as the views of the Board of Pharmacy, MPhA, the author, the editor, the typist, or anybody who came in contact with this article before publication. Even if maybe just a little bit of reality creeps in.

The Board of Pharmacy has begun a complete review of the pharmacy laws under which the profession operates. It would be nice to think that the Board -- or anyone -- could be all things to all people. So, just for a page or two, let's pretend that everyone gets what they want in the changes to a few selected sections. Herewith are the wish lists.

§ 12-202 Membership

For the Board: increase Board membership to 12 pharmacists who would all evenly share the workload. All members would be able to dedicate their full time to the Board.

For MPhA: decrease the membership to three members: one blind, one unable to speak, and the other deaf (a bunch of monkeys?) to alleviate the MPhA's concerns that the Board has too much power.

For the Public: 22 members spending all their time punishing pharmacists for mistakes.

§ 12-205 Powers and duties

For the Board: The power to use their judgement without worrying about lawyers finding ways around the law; without politics coming into play; and with complete cooperation from other health occupation boards to see that their licensees cooperate with the Board of Pharmacy.

For the MPhA: all of the above, but only when they agree with it.

For the Public: The power to cut off pharmacists' appendages of varying degrees of importance whenever they charge high prices. Male pharmacists better be extra sure to charge low prices (they have longer noses than females on the average).

§ 12-206 Board of Pharmacy Fund

For the Board: The fund may be increased to any amount and the money used to make the Board more efficient without regard for oversight by the State.

For the MPhA: The Board may be funded in any way that does not cost their members more than \$10 in license fees every fourth year.

For the Public: who cares, the pharmacists pay.

For the Health Care Access

Commission: the fund will pay a multiple of 10 times what pharmacists are now taxed to allow them to operate with an even bigger budget.

§ 12-207 Good faith exemption from civil liability.

For the Board: Total exemption, we define good faith.

For the Public: Let the lawyers decide.

For the Lawyers: Surrre, you get exempted from our right to sue.

12-304 Examinations.

For Senior Students: all examinations will have an answer sheet attached.

For the Board: Surrre it will.

12-309 Continuing Education

For the Board: All CE will taken in such a way that pharmacists absorb at least 30 hours of needed knowledge each renewal period.

For the School of Pharmacy: All CE will be taken at the school with full tuition paid and no credit granted unless the pharmacist is considered to finish the course on an educational level with full professors who are not encumbered by having to fill prescriptions for a living 50 hours a week.

For the Public: Just assure us that pharmacists will not make errors and will have the knowledge base to help us.

For brand name companies: All CE provided will be about why pharmacists should only dispense branded drugs.

For the Generic Companies: Anything other than that.

§ 12-310 Reinstatement of expired licenses.

For those pharmacists caught this year with expired licenses: total and absolute clemency.

For the University Health System and Shock Trauma: to be allowed to employ these pharmacists.

§ 12-313 Grounds for Denials, Reprimands, Suspensions, Revocations and Possible Whippings.

For the Board: whatever we see fit to do when someone embarrasses the profession.

For the offending person: a party to celebrate complete exoneration from everything.

For the MPhA: something in between

For the lawyers: whatever it takes to get more billable hours.

§ 12-317 Pharmacist Rehabilitation Committees

For the Board: the Committee shall obtain their own funding and follow all persons being disciplined by the Board no matter what the reason for the discipline.

For the Committee: The Board will completely fund their activities including trips to hear the Mormon Tabernacle Choir every year.

§ 12-508. Substitution of generic products.

For the Board: Expand this section to allow pharmacists to help provide less expensive quality treatments through therapeutic substitution.

For the MPhA: The same.

For the physicians: Back from the future to the past - pharmacists do what physicians say and



no back talk.

For the brand companies: Agreement because they could then offer lower prices to community pharmacists to get their product used (I told you this was a fantasy wish list).

§ 12-511 Guidelines for unauthorized refills

For the Board: Perhaps a little more leeway for what amounts to emergency help for the public.

For the public: Those who don't want to pay the doctor - unlimited refills.

For the MPhA: Perhaps a little more of going back from the future. Is anyone reading this old enough to remember when pharmacists were not prohibited from using professional judgement on refills? That, like other privileges such as the right to use judgement on Schedule V cough syrups, was lost when too many of our profession misused the responsibility.

§ 12-512 Patient Counseling

For the Board: Undecided

For the MPhA: increased counseling with mandatory payment from patients, insurers, HMO's

For the insurers and HMO's: Surrre, we will pay more.

New Section: Technicians:

For the Board: Maybe just have the issue go away.

For pharmacists: Technicians get the responsibility, pharmacists get the pay.

For the MPhA: A minimum ratio of 3 pharmacist to one tech.

For Mail order companies: A minimum ratio of 30 techs to one pharmacist.

For the technicians: Who?

For Robotics: What?

§ 12.601 Manufacturer and Distribution Permits.

For the Board: increase their permit costs enough so we don't have to worry about collecting from 6,500 pharmacists.

For the MPhA: Yeah!

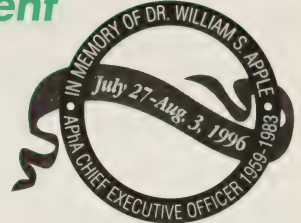
Reg 10:34:01 Formal hearings

For the Board: Hearings will be short, with only pertinent points heard, everyone showing up on time, and no delaying or muddying tactics by the attorneys.

For the lawyers: The reverse. A guy has to make a living somehow.

For the pharmacist involved: A law requiring them to admit what they have done wrong even when they think they have a loophole to wiggle out of. (I think I forgot whose fantasy this is.)

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For the patients again: ..at no charge for the advise and
acquisition cost for the medicine.

Back to the owners: No, not that part.

All of the above is the responsibility of the author
and does not necessarily reflect the thinking of the
Board of Pharmacy or any other members or even
David Miller.

It includes some frustrations which Board members
may have while trying to do a good job with limited
time and resources; the desire of MPhA to protect the
professional interests of pharmacists; and the increased
feeling the public has that pharmacists are trusted to
perform their duties at the highest level.

It's also been fun fantasizing on other peoples
fantasies, perhaps the last article I will be trusted to
write. I hope you enjoyed it, too! And, that you get
everything you want on your wish list this year.

MP

Continuing Education Quiz

December 1995 -- Allergic Rhinitis Part II

This month's questions are taken from the article on allergic rhinitis that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. There is **no charge** for this quiz for MPhA members (non-members \$5.00). The completed quiz for this issue must be received by December 31, 1996. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly. **ACPE 144-999-95-052-H01.**

Name _____

Address _____

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1. Consumers who ask for a recommendation of an antihistamine-containing OTC should be told that their physician should first be contacted if they have any of the following diseases *except*:
 - a. chronic bronchitis
 - b. enlarged prostate
 - c. glaucoma
 - d. hypertension
2. When compared to first-generation antihistamines, the second-generation antihistamines cause less sedation because they:
 - a. are composed of a significantly larger molecule.
 - b. cross the blood-brain barrier to a lesser extent.
 - c. primarily antagonize H² receptors rather than H¹ receptors.
 - d. act as sympathomimetics amines.
3. Rhinitis medicamentosa is most often associated with which of the following?
 - a. Cromolyn spray
 - b. Intranasal corticosteroids
 - c. Systemic antihistamines
 - d. Topical decongestants
4. The group of antihistamines which causes the most marked drowsiness is the derivatives of:
 - a. ethanolamine
 - b. ethylenediamine
 - c. alkylamine
 - d. piperidine
5. A commercially available product containing a member of the group referred to in question #4 is:
 - a. Actifed
 - b. Pyribenzamine
 - c. Benadryl
 - d. Vistaril
6. The active ingredient in Beconase AQ nasal spray is:
 - a. beclomethasone
 - b. budesonide
 - c. cromolyn
 - d. triamcinolone
7. Which of the following is most likely to act by stabilizing mast cells and preventing the release of histamine by blocking the transport of calcium across their membranes?
 - a. Antihistamines
 - b. Corticosteroids
 - c. Cromolyn
 - d. Decongestants
8. Consumers who ask for a recommendation of an OTC decongestant should be told that their physician should first be contacted if they have any of the following diseases *except*:
 - a. diabetes.
 - b. hay fever.
 - c. heart disease
 - d. thyroid disease.
9. Relief of symptoms of allergic rhinitis with the use of intranasal corticosteroids is most likely to occur in:
 - a. one to two hours.
 - b. one to two days.
 - c. one to two weeks.
 - d. one to two months.
10. Which of the following is the treatment of first choice for patients with allergic rhinitis?
 - a. Antihistamines
 - b. Cromolyn
 - c. Corticosteroids
 - d. Immunotherapy

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1804, Washington DC 20013 or call (301) 341-8700, ext. 1428. EOE.

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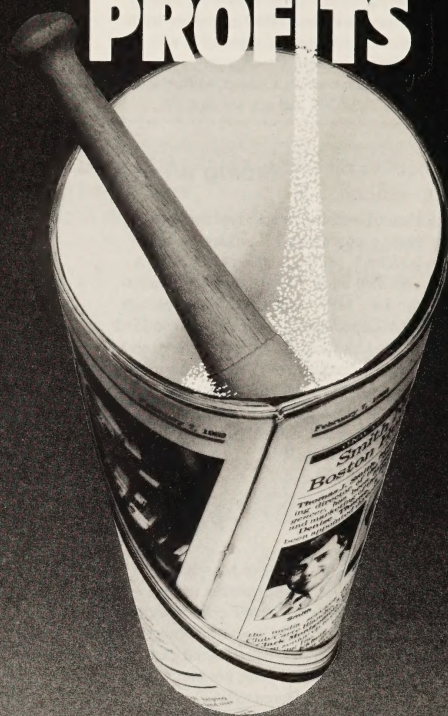
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